California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE
The Legislation and Regulation Committee did not meet during the last quarter.

PART II: LEGISLATION REPORT

a. Board Sponsored Legislation

ATTACHMENT 1

SB 431 (Emmerson): Pharmacies - Regulation

In January 2010, the board voted to pursue legislation to improve the board's enforcement tools as well as to better define the return of medicine via reverse distributors. These provisions are incorporated in SB 431. Below are the specific code sections:

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure
   Amend to clarify that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft or impairment. Require a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.
b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records
   Amend to specify the time period for which records shall be provided to the board when requested by an inspector or authorized representative of the board.
c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
   Require that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist related services to Californians.
d. §4040.5 – Reverse Distributor
   Specifies that a reverse distributor may not accept previously dispensed medicine and that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler. Defines "dispensed" for purposes of this section only. This provision was approved in concept only by the board in January 2009.
e. §4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
   Specifies that records documenting the return of drugs to a wholesaler or reverse distributor must include the quantity or weight of the drug being returned, the date returned and the name(s) to which the drugs were provided. Specifies that records documenting the return of drugs to a licensed integrated waste hauler shall include a list of the volume in weight and measurement, and the date and name of the hauler. Defines "licensed integrated waste hauler"

for purposes of this section only. This provision was approved in concept only by the board in January 2009.

f. §4126.5 – Furnishing Dangerous Drugs by a Pharmacy
Authorizes a pharmacy to furnish drugs to a licensed integrated waste hauler. Needs to authorize a pharmacy to accept returned product from a consumer in the event of a product recall.

This bill has been amended twice to address concerns. Board staff continues to advocate this legislation and is working with the author's office to address concerns raised.

Current Status: This bill passed out of Assembly Health Committee on July 6, 2011 and is scheduled to be heard in the Assembly Appropriations Committee August 17, 2011.

Senate Bill 943 (Senate Committee on Business, Professions and Economic Development) Omnibus

At the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code section 4200. This provision is contained in Senate Bill 943.

Current Status: This measure passed out of the Assembly Business, Professions and Consumer Protection Committee on July 6 and is scheduled to be heard in the Assembly Appropriations Committee on August 17, 2011.

ATTACHMENT 1 contains a copy of SB 431 as well as relevant portions of SB 943.

b. Legislation Introduced Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. Board of Pharmacy/Licensing

ATTACHMENT 2

AB 377 (Solorio) Pharmacy: Centralized Hospital Packaging

Version: As amended, April 14, 2011

Summary: This bill provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified.

Board Position: Support If Amended

Recent Action: This bill is scheduled to be heard in the Senate Appropriations Committee on August 15, 2011.

Recent Update: Board staff was just advised by CSHP that this will be a two-year bill.

Attachment 2 contains a copy of the bill in its current form along with an analysis of the measure.

Currently Two-Year Bills

AB 847 (Lowenthal, Bonnie): Pharmacies: Clinics

Version: As Introduced March 10, 2011

Summary: Would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a clinic operating under these provisions be licensed by the California State Board of Pharmacy and would make that licensure optional.

Board Position: None

SB 632 (Emmerson) Pharmacy

Version: As Amended March 24, 2011

Summary: Would prohibit a pharmacist from interchanging or substituting an opioid analgesic drug, as defined, for an opioid analgesic drug incorporating a tamper resistant technology, as defined, unless the opioid analgesic drug to be interchanged or substituted is described on a list to be prepared by the board. In those situations where the drug is not on the board's list, the bill would require the pharmacist to obtain consent from the prescriber prior to an interchange or substitution.

Board Position: None

2. Controlled Substances

ATTACHMENT 3

AB 507 (Hayashi): Pain Management

Version: As amended, July 1, 2011

Summary: In its current form, this measure would conform findings and declarations and other references to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

History: As originally introduced, this measure repealed provisions in existing law which permit the Department of Justice (DOJ) to employ a physician to interview and examine any patient in connection with the prescription possession or use of a controlled substance, require the patient to submit to the interview and examination, and permit the physician to testify in prescribed administrative proceedings. Prior to the May Board Meeting, this measure has been amended twice since the committee reviewed it. The first amendments occurred on April 13, 2011 and removed the proposed changes to the board's unprofessional conduct statute, B&PC 4301. The bill was again amended on April 27, 2011 and again proposed a change to B&PC 4301(d).

Board Position: Oppose (April 27, 2011 version)

Recent Update: This measure has been amended again on June 20, 2011 and July 1, 2011 and proposed changes to the board's unprofessional conduct statute were removed.

Current Status: Hearing scheduled on August 15, 2011 in the Senate Appropriations Committee.

Attachment 3 contains a copy of the bill and an analysis of the measure.

3. Reporting Requirements/Records

ATTACHMENT 4

AB 1280 (Hill): Ephedrine - Retail Sale

Version: As amended, May 26, 2011

Summary: The bill contains provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified. This bill proposes a real-time tracking system beginning on or after July 1, 2012 through December 2018.

Board Position: Watch

Current Status: Hearing scheduled for August 15, 2011 in Senate Appropriations Committee.

Recent Update: This measure was amended twice since the May Board Meeting.

SB 360 (DeSaulnier): Controlled Substance Utilization Review and Evaluation System

Version: As amended, July 7, 2011

Summary: This bill would revise Schedule I and Schedule II to add additional opiates, revise Schedule III to add additional depressants, anabolic steroid products, and materials, compounds, mixtures, or preparations containing chorionic gonadotropin (a hormone), and Schedule IV to add additional depressants and stimulants.

Board Position: Watch

Recent Action: Hearing scheduled for August 17, 2011 in Senate Appropriations Committee.

Recent Update: This measure has been amended twice since the May Board Meeting. Most notably, this measure would specify reporting to the CURES system would be linked to the federal schedule of controlled drugs, not the state schedule. Board staff has identified the areas where the state and federal schedules vary. More information is included in the bill analysis for this measure.

SB 850 (Leno) Medical Records: Confidential Information

Version: As Amended, June 22, 2011

Summary: This bill would require an electronic health or medical record system to automatically record and preserve any change or deletion of electronically stored medical information, and would require the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was made to the medical information.

Board Position: None. The board has not previously discussed this measure.

Current Status: Hearing scheduled for August 17, 2011 in the Assembly Appropriations Committee.

Attachment 4 contains a copy of each of the above measures as well as an analysis.

Currently Two-Year Bills

SB 315 (Wright) Ephedrine and Pseudoephedrine

Version: As Introduced February 14, 2011

Summary: This bill would classify pseudoephedrine as a prescription drug.

Board Position: Support

4. Healing Arts/DCA

ATTACHMENT 5

SB 541 (Price) Regulatory boards: Expert Consultants

Version: As amended, June 21, 2011

Summary: This bill would authorize boards to enter into an agreement with an expert consultant, subject to the standards regarding personal service contracts described, to provide enforcement and examination assistance. The bill would require each board to establish policies and procedures for the selection and use of these consultants.

Board Position: Support (April 13, 2011 version)

Recent Action: This bill was amended June 21, 2011 to specify that the proposed change shall not be construed to expand the scope of service of an expert.

Current Status: Hearing scheduled for August 17, 2011 in the Assembly Appropriations Committee.

Attachment 5 contains a copy of this measure and a bill analysis.

Currently Two-Year bills

AB 675 (Hagman) Continuing Education

Version: As Amended April 5, 2011

Summary: This bill would specify that continuing education or competency courses that advance or promote labor organizing on behalf of a union, or that advance or promote statutory or regulatory changes, political candidates, political advocacy, or political strategy shall not be considered content relevant to the practice regulated by the board and shall not be acceptable for meeting requirements for licensure renewal.

Board Position: None

AB 958 (Berryhill) Regulatory boards: Limitation periods

Version: As introduced February 18, 2011

Summary: This bill would require the board to file an accusation within one year after the board discovers the violation.

Board Position: None

SB 544 (Price): Healing Arts

Version: As amended, April 14, 2011

Summary: The bill would require cooperation between state agencies and all boards within the department when investigating a licensee, and would require a state agency to provide to the board all licensee records in the custody of the state agency. The bill would require all local and state law enforcement agencies, state and local governments, state agencies, licensed health care facilities, and any employers of any licensee to provide licensee records to any board within the department upon request by that board, and would make an additional requirement specific to the Department of Justice.

Board Position: None

SB 667 (Wyland) Naturopathic Doctors

Version: As amended, March 31, 2011

Summary: This bill would provide that a naturopathic doctor is not prohibited from ordering, prescribing, or administering a nonprescription substance that becomes a substance requiring a prescription based solely on its route of administration.

Board Position: None

5. Other

ATTACHMENT 6

AB 389 (Mitchell): Bleeding disorders - blood clotting products

Version: As amended, March 30, 2011

Summary: This bill would impose specified requirements on providers of blood clotting products for home use for products used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia.

Board Position: Watch

Current Status: Hearing scheduled for August 15, 2011 in the Senate Appropriations Committee.

AB 604 (Skinner): Needle Exchange Programs

Version: As amended, July 14, 2011

Summary: This bill would authorize, until January 1, 2019, the State Department of Public Health to approve certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

Board Position: Support (April 5, 2011 version)

Recent Update: Recent amendments to this measure put a sunset date of January 1, 2019 on the authority of CDPH to NEP programs.

SB 41 (Yee): Disposal of Hypodermic Needles and Syringes

Version: As amended, June 28, 2011

Summary: This bill would allow, until January 1, 2015, a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 18 years of age or older. The bill addresses the storage of products to ensure they would be available only to authorized personnel, would require that disposal options are provided to consumers, and would require pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

Board Position: Support If Amended

Recent Update: This measure has been amended three times since the May 2011 Board Meeting.

Current Status: Ordered to third reading in the Assembly.

SB 514 (Simitian): Dextromethorphan - sale to minors prohibited

Version: As amended, May 10, 2011

Summary: This bill would make it illegal to sell dextromethorphan to a person under the age of 18 without a prescription.

Board Position: Support

Recent Action: This measure was amended on May 10, 2011 to specify that an infraction of this provision may be punishable by a fine not to exceed $250.00.

Current Status: Ordered to third reading in the Assembly.

A copy of each bill and an analysis are provided for each measure in **Attachment 6**.

6. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

Attachment 7

The board will have the opportunity to review additional legislation that affects the practice of pharmacy or the board's jurisdiction. One such measure was identified earlier this will and will be brought to the board for consideration. Additional items may be discussed at well if identified.

AB 1424 (Perea) Franchise Tax Board: Delinquent Tax Debt

Summary: This bill would require the State Board of Equalization and the Franchise Tax Board to each make available a list of the 500 largest tax delinquencies described above at least twice each calendar year. This bill would require the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and licence number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. This bill would specify that a license may be suspended for failure to pay tax delinquencies.

Current Status: Hearing scheduled for August 15, 2011 in Senate Appropriations Committee.

A copy of the bill and analysis are provided in **Attachment 7**.

AMENDED IN SENATE MAY 10, 2011

AMENDED IN SENATE APRIL 11, 2011

SENATE BILL No. 431

Introduced by Senator Emmerson

February 16, 2011

An act to amend Sections 4081, 4104, 4105, ~~4112, and 4126.5~~ *and 4112* of, and to add Section 4126.7 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 431, as amended, Emmerson. Pharmacies: regulation.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for administering and enforcing the provisions of that law, including the licensure of pharmacies, as defined, and nonresident pharmacies that ship, mail, or deliver controlled substances or dangerous drugs or devices, as defined, into this state. Under existing law, a reverse distributor is any person who acts as an agent for a pharmacy, drug wholesaler, manufacturer, or other entity by receiving, inventorying, and managing the disposition of outdated or nonsalable dangerous drugs. A knowing violation of the Pharmacy Law is a crime. ~~Existing law provides for the registration of hazardous waste haulers, as defined.~~

This bill would, *except as specified*, prohibit a reverse distributor from accepting the return of dangerous drugs that have been dispensed to a patient that are later returned by the patient or patient's agent to a pharmacy, as specified~~, and would authorize only hazardous waste haulers to handle or dispose of those drugs~~.

Existing law requires that each pharmacy establish procedures for addressing the theft, diversion, or self-use of dangerous drugs by a

licensed individual employed by or with the pharmacy, and that every pharmacy report to the board within 30 days of the receipt or development of certain information affecting the ability of those individuals to practice the profession or occupation authorized by their license, as specified. Existing law requires an entity licensed by the board to retain records of the acquisition and disposition of dangerous drugs and devices in a specified manner. *Existing federal law requires registrants distributing specified controlled substances to conduct an inventory of controlled substances every 2 years.*

This bill would instead require a pharmacy to report and provide to the board, within 14 days of the receipt or development thereof, the information described above regarding the ability of licensed individuals employed by or with the pharmacy to practice the profession or occupation authorized by their license. The bill would require ~~a pharmacy to conduct an audit of the theft, diversion, or self-use of dangerous drugs by a licensed individual employed by or with the pharmacy and provide, as specified, the board with a copy of the audit and its results.~~ *the report to include specified detailed information, including the date of the last controlled substances inventory, and would require the pharmacy to prepare and submit an audit relating to the report upon the request of the board.* The bill would also require an entity licensed by the board to provide records to designated persons within ~~72 hours~~ *3 business days* of the time of the request, unless that timeframe is extended by the board, *as specified*. The bill would prohibit a pharmacist whose license was revoked by the board to perform pharmacy duties, as specified, for a nonresident pharmacy.

Existing law requires all records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices to be at all times during business hours open to inspection by authorized officers of the law and preserved at least 3 years from the date of making. Existing law requires every person or entity who maintains a stock of dangerous drugs or dangerous devices to keep a current inventory.

This bill would require that any record pertaining to the return of dangerous drugs to a wholesaler, reverse distributor, or hazardous waste hauler include specified information, including the quantity or weight of the drugs returned.

Because this bill would specify additional requirements under the Pharmacy Law, a violation of which is a crime, it would impose a state-mandated local program by creating additional crimes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Any record pertaining to the return of dangerous drugs to a wholesaler or provided to a reverse distributor shall document the quantity or weight of the drugs returned, the date the drugs were

returned, and the name of the reverse distributor or wholesaler to whom the drugs were provided.

(e) Any record pertaining to the return of dangerous drugs to a hazardous waste hauler, as described in Section 117660 of the Health and Safety Code, shall list the volume in weight or measurement of the pharmaceutical waste returned, the date the waste was returned, and the name of the hazardous waste hauler to whom the waste was provided.

SEC. 2. Section 4104 of the Business and Professions Code is amended to read:

4104. (a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within 14 days of the receipt or development thereof, the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

~~(d) The pharmacy shall conduct an audit to determine the quantity and type of dangerous drugs stolen, diverted, or used by a licensed individual employed by or with the pharmacy. The pharmacy shall submit to the board a copy of the audit within 30 days of the initial report to the board regarding the evidence described in subdivision (c).~~

(d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

SEC. 3. Section 4105 of the Business and Professions Code is amended to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy

and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within ~~72 hours~~ *three business days* of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 *calendar* days from the date the records were requested. A request for an extension of time is subject to the approval of the board. *An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.*

SEC. 4. Section 4112 of the Business and Professions Code is amended to read:

4112. (a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or

licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

~~SEC. 5. Section 4126.5 of the Business and Professions Code is amended to read:~~

~~4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:~~

~~(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.~~

~~(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.~~

~~(3) A licensed wholesaler acting as a reverse distributor.~~

~~(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.~~

~~(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.~~

~~(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.~~

~~(7) To another pharmacy under common control.~~

~~(8) A hazardous waste hauler, as described in Section 117660 of the Health and Safety Code, for the sole purpose of waste disposal of pharmaceutical waste returned to the pharmacy by a patient or patient's agent.~~

~~(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.~~

~~(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under~~

~~this section shall be deposited into the Pharmacy Board Contingent Fund.~~

~~(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.~~

~~SEC. 6.~~

SEC. 5. Section 4126.7 is added to the Business and Professions Code, to read:

4126.7. (a) A reverse distributor shall not accept the return of dangerous drugs that have been dispensed to a patient ~~that are later returned by the patient or the patient's agent to the pharmacy or another licensed entity.~~ *and returned to the pharmacy unless the dangerous drugs were dispensed in a sealed or tamper-evident package and there is no evidence that the package was opened, damaged, or otherwise tampered with prior to its return to the pharmacy. Records of these returned dangerous drugs shall be kept by the pharmacy.*

~~(b) Dangerous drugs returned by a patient or a patient's agent to a pharmacy, if accepted by the pharmacy, may be picked up or handled only by a hazardous waste hauler, as described in Section 117660 of the Health and Safety Code.~~

~~(c)~~

(b) For purposes of this section, "dispensed" means that the dangerous drugs have been provided to the patient or patient's agent and taken from a pharmacy.

~~SEC. 7.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN ASSEMBLY JULY 12, 2011

AMENDED IN ASSEMBLY JUNE 13, 2011

AMENDED IN SENATE MAY 19, 2011

AMENDED IN SENATE MAY 11, 2011

SENATE BILL No. 943

Introduced by Committee on Business, Professions and Economic Development (Senators Price (Chair), Corbett, Correa, Emmerson, Hernandez, Negrete McLeod, Vargas, Walters, and Wyland)

March 31, 2011

An act to amend Sections ~~1915,~~ 1916, 1917, 1917.2, 1918, 1922, 1927, 1950, 1952, 1955, 1957, 1959, 1961, 1962, 1963, 1966.1, 2736.5, 2836.2, 2936, 3519, 3575, 4200, 4836.1, 4980.36, 4980.37, 4980.40.5, 4980.42, 4980.45, 4982.25, 4989.54, 4990.38, 4992.3, 4992.36, 4996.13, 4996.24, 4999.12, and 4999.90 of, to add Sections 1902.1, 4999.91, and 4999.455 to, and to repeal Section 1945 of, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 943, as amended, Committee on Business, Professions and Economic Development. Healing arts.

Existing law provides for the licensure and regulation of various healing arts licensees by boards within the Department of Consumer Affairs.

(1) Existing law, the Dental Practice Act, provides for the licensure and regulation of registered dental hygienists, registered dental hygienists in alternative practice, and registered dental hygienists in extended functions by the Dental Hygiene Committee of California

within the Dental Board of California. ~~Existing law provides that no person other than those licensees or a licensed dentist may engage in the practice of dental hygiene or perform dental hygiene procedures on patients, including, but not limited to, supragingival and subgingival scaling, dental hygiene assessment, and treatment and planning.~~

~~This bill would add to that enumerated list periodontal record evaluation, administration of local anesthesia, nitrous oxide-oxygen analgesia, and gingival soft tissue curettage.~~

Existing law requires applicants for licensure to provide fingerprint images for submission to governmental agencies, in order to, among other things, establish the identity of the applicant.

This bill would require applicants to submit electronic fingerprint images.

Existing law requires the committee to license as a registered dental hygienist, a registered dental hygienist in extended functions, or a registered dental hygienist in alternative practice a person who meets certain educational, training, and examination requirements.

This bill would additionally require these applicants to complete an application and pay required application fees. ~~The bill would also require a registered dental hygienist to have completed committee-approved instruction in gingival soft tissue curettage, nitrous oxide-oxygen analgesia, and local anesthesia.~~

Existing law, until January 1, 2012, requires the committee to license as a registered dental hygienist a 3rd- or 4th-year dental student who is in good standing at an accredited California dental school, who satisfactorily performs on a clinical examination and an examination in California law and ethics as prescribed by the committee, and who satisfactorily completes a national written dental hygiene examination approved by the committee.

This bill would extend those provisions until January 1, 2014.

Under existing law, a licensee may have his or her license revoked or suspended, or may be reprimanded or placed on probation by the committee, for conviction of a crime substantially related to the licensee's qualifications, functions, or duties. Existing law authorizes the committee to order a license suspended or revoked or to decline to issue a license if certain procedural events occur.

This bill would additionally authorize the committee to reprimand a licensee or order a license placed on probation.

Under existing law, a licensee or health care facility that fails to comply with a specified request from the committee for a patient's

dental hygiene records is subject to a $250 per day civil penalty for each day that the records have not been produced, as specified.

This bill would additionally require licensees and health care facilities to comply with a request for a patient's dental records and would make them subject to a civil or administrative penalty or fine up to a maximum of $250 per day for each day that the records have not been produced, as specified.

(2) Existing law, the Nursing Practice Act, provides for the licensure and regulation of registered nurses by the Board of Registered Nursing.

Existing law requires applicants for licensure as a registered nurse to meet certain educational requirements, to have completed specified courses of instruction, and to not be subject to denial of licensure under specified circumstances. Existing law authorizes applicants who have served on active duty in the medical corps in the United States Armed Forces to submit a record of specified training to the board for evaluation in order to satisfy the courses of instruction requirement. Under existing law, if the applicant satisfies the other general licensure requirements and if the board determines that both education and experience establish competency to practice registered nursing, the applicant shall be granted a license upon passing a certain examination.

This bill would limit that board determination to be based on education only.

(3) Existing law, the Physician Assistant Practice Act, provides for the licensure and regulation of physician assistants by the Physician Assistant Committee. Existing law requires the committee to issue a license to a physician assistant applicant who, among other things, provides evidence of either successful completion of an approved program, as defined, or a resident course of professional instruction meeting certain requirements.

This bill would instead require applicants to provide evidence of successful completion of an approved program, as defined.

(4) Existing law provides for the registration and regulation of polysomnographic technologists by the Medical Board of California. Existing law requires the board to promulgate regulations relative to the qualifications for the registration of individuals as certified polysomnographic technologists. Existing law specifies that the qualifications for a certified polysomnographic technologist includes meeting certain educational requirements and the passage of a national certifying examination. Existing law authorizes, for a specified period, the examination requirement to be satisfied if the applicant submits

proof that he or she has been practicing polysomnography for at least 5 years, as specified.

This bill would authorize, for a specified period, all of these qualifications to be satisfied if the applicant submits proof that he or she has been practicing polysomnography for at least 5 years, as specified.

(5) Existing law, the Veterinary Medicine Practice Act, until January 1, 2012, authorizes a registered veterinary technician and an unregistered assistant to administer a drug, including, but not limited to, a drug that is a controlled substance, except for the induction of anesthesia, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of the veterinarian.

This bill would extend the operation of that provision to January 1, 2013.

(6) Under existing law, the Board of Behavioral Sciences is responsible for the licensure, registration, and regulation of, among others, marriage and family therapists, licensed clinical social workers, and licensed professional clinical counselors.

(A) Existing law, the Marriage and Family Therapist Act, provides for the licensure and regulation of marriage and family therapists and makes a violation of the act a crime. Existing law, with respect to marriage and family therapists and marriage and family therapist interns, requires an applicant to possess a doctoral or master's degree in any of various disciplines, including, but not limited to, marriage, family, and child counseling.

This bill would add couple and family therapy to that list of acceptable disciplines.

Existing law requires that degree to contain a specified number of units of instruction that includes practicum involving direct client contact of a specified number of hours of face-to-face experience counseling individuals, couples, families, or groups and authorizes a portion of those hours to be gained performing client centered advocacy, as defined.

This bill would revise and recast that requirement and would authorize that portion of hours to be gained performing either client centered advocacy or face-to-face experience counseling individuals, couples, families, or groups.

Existing law authorizes a licensed professional in private practice meeting certain requirements to supervise or employ no more than a

total of 2 individuals registered as either a marriage and family therapist intern or associate clinical social worker.

This bill would authorize such a licensed professional to supervise or employ no more than a total of 3 individuals and would add clinical counsel interns to that list. Because the bill would change the definition of a crime, it would thereby impose a state-mandated local program.

Under existing law, a marriage and family therapy corporation may employ no more than a total of 2 individuals registered as either a marriage and family therapist intern or associate clinical social worker for each employee. Existing law prohibits the corporation from employing more than 10 individuals registered as either a marriage and family therapist intern or associate clinical social worker.

This bill would authorize the corporation to employ no more than a total of 3 individuals and would add clinical counsel interns to that list. The bill would also authorize the corporation to employ no more than 15 registrants and would include clinical counsel interns.

(B) The Clinical Social Worker Practice Act provides for the licensure and regulation of social workers and makes a violation of the act a crime. Under existing law, qualified members of other professional groups may do work of a psychosocial nature consistent with the standards and ethics of their respective professions.

This bill would specify that licensed professional clinical counselors may do such work.

Existing law authorizes a licensee in private practice meeting certain requirements to supervise or employ no more than a total of 2 individuals registered as either a marriage and family therapist intern or associate clinical social worker.

This bill would authorize that licensed professional to supervise or employ no more than a total of 3 individuals and would add clinical counsel interns to that list.

Under existing law, a licensed clinical social workers' corporation may employ no more than a total of 2 individuals registered as either a marriage and family therapist intern or associate clinical social worker for each employee who has satisfied certain requirements. Existing law prohibits the corporation from employing more than 10 individuals registered as either a marriage and family therapist intern or associate clinical social worker.

This bill would authorize the corporation to employ no more than a total of 3 individuals and would add clinical counsel interns to that list.

The bill would also authorize the corporation to employ no more than 15 registrants and would include clinical counsel interns.

By changing the definition of crimes, the bill would impose a state-mandated local program.

(C) Existing law, the Licensed Professional Clinical Counselor Act, provides for the licensure and regulation of professional clinical counselors and makes a violation of the act a crime. Existing law generally authorizes the board to take certain enforcement actions against licensees for a violation of the act.

This bill would authorize the board to deny any application, or to suspend or revoke any license or registration, for specified reasons.

The bill would also authorize a licensee in private practice meeting certain requirements to supervise or employ no more than a total of 3 individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. The bill would authorize professional clinical counselor corporation to employ no more than a total of 3 individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker for each employee. The bill would prohibit the corporation from employing more than 15 individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. Because a violation of these requirements would constitute a crime, the bill would impose a state-mandated local program.

The bill would make other conforming and technical changes, including technical changes to the Psychology Licensing Law and the Pharmacy Law.

(7) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1902.1 is added to the Business and Professions Code, to read:

1902.1. Protection of the public shall be the highest priority for the committee in exercising its licensing, regulatory, and

disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

~~SEC. 2. Section 1915 of the Business and Professions Code is amended to read:~~

~~1915. No person other than a registered dental hygienist, registered dental hygienist in alternative practice or registered dental hygienist in extended functions, or a licensed dentist may engage in the practice of dental hygiene or perform dental hygiene procedures on patients, including, but not limited to, supragingival and subgingival scaling, dental hygiene assessment, periodontal record evaluation, administration of local anesthesia, nitrous oxide-oxygen analgesia, gingival soft tissue curettage, and treatment planning, except for the following persons:~~

~~(a) A student enrolled in a dental or a dental hygiene school who is performing procedures as part of the regular curriculum of that program under the supervision of the faculty of that program.~~

~~(b) A dental assistant acting in accordance with the rules of the dental board in performing the following procedures:~~

~~(1) Applying nonaerosol and noncaustic topical agents.~~

~~(2) Applying topical fluoride.~~

~~(3) Taking impressions for bleaching trays.~~

~~(c) A registered dental assistant acting in accordance with the rules of the dental board in performing the following procedures:~~

~~(1) Polishing the coronal surfaces of teeth.~~

~~(2) Applying bleaching agents.~~

~~(3) Activating bleaching agents with a nonlaser light-curing device.~~

~~(4) Applying pit and fissure sealant.~~

~~(d) A registered dental assistant in extended functions acting in accordance with the rules of the dental board in applying pit and fissure sealants.~~

~~(e) A registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions licensed in another jurisdiction, performing a clinical demonstration for educational purposes.~~

~~SEC. 3.~~

SEC. 2. Section 1916 of the Business and Professions Code is amended to read:

1916. (a) An applicant for licensure under this article shall furnish electronic fingerprint images for submission to state and federal criminal justice agencies, including, but not limited to, the Federal Bureau of Investigation, in order to establish the identity of the applicant and for the other purposes described in this section.

(b) The committee shall submit the fingerprint images to the Department of Justice for the purposes of obtaining criminal offender record information regarding state and federal level convictions and arrests, including arrests for which the Department of Justice establishes that the person is free on bail or on his or her own recognizance pending trial or appeal.

(c) When received, the Department of Justice shall forward to the Federal Bureau of Investigation requests for federal summary criminal history information received pursuant to this section. The Department of Justice shall review the information returned from the Federal Bureau of Investigation and compile and disseminate the response to the committee.

(d) The Department of Justice shall provide a response to the committee pursuant to subdivision (p) of Section 11105 of the Penal Code.

(e) The committee shall request from the Department of Justice subsequent arrest notification service, as provided pursuant to Section 11105.2 of the Penal Code.

(f) The information obtained as a result of the fingerprinting shall be used in accordance with Section 11105 of the Penal Code, and to determine whether the applicant is subject to denial of licensure pursuant to Division 1.5 (commencing with Section 475) or Section 1943.

(g) The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this section.

~~SEC. 4.~~

SEC. 3. Section 1917 of the Business and Professions Code is amended to read:

1917. The committee shall grant initial licensure as a registered dental hygienist to a person who satisfies all of the following requirements:

(a) Completion of an educational program for registered dental hygienists, approved by the committee, accredited by the Commission on Dental Accreditation, and conducted by a degree-granting, postsecondary institution.

(b) Satisfactory performance on the state clinical examination, or satisfactory completion of the dental hygiene examination given by the Western Regional Examining Board or any other clinical dental hygiene examination approved by the committee.

(c) Satisfactory completion of the National Dental Hygiene Board examination.

(d) Satisfactory completion of the examination in California law and ethics as prescribed by the committee.

(e) Submission of a completed application form and all fees required by the committee.

~~(f) Satisfactory completion of committee-approved instruction in gingival soft tissue curettage, nitrous oxide-oxygen analgesia, and local anesthesia.~~

~~SEC. 5.~~

SEC. 4. Section 1917.2 of the Business and Professions Code is amended to read:

1917.2. (a) The committee shall license as a registered dental hygienist a third- or fourth-year dental student who is in good standing at an accredited California dental school and who satisfies the following requirements:

(1) Satisfactorily performs on a clinical examination and an examination in California law and ethics as prescribed by the committee.

(2) Satisfactorily completes a national written dental hygiene examination approved by the committee.

(b) A dental student who is granted a registered dental hygienist license pursuant to this section may only practice in a dental practice that serves patients who are insured under Denti-Cal, the Healthy Families Program, or other government programs, or a dental practice that has a sliding scale fee system based on income.

(c) Upon receipt of a license to practice dentistry pursuant to Section 1634, a registered dental hygienist license issued pursuant to this subdivision is automatically revoked.

(d) The dental hygienist license is granted for two years upon passage of the dental hygiene examination, without the ability for renewal.

(e) Notwithstanding subdivision (d), if a dental student fails to remain in good standing at an accredited California dental school, or fails to graduate from the dental program, a registered dental hygienist license issued pursuant to this section shall be revoked.

The student shall be responsible for submitting appropriate verifying documentation to the committee.

(f) The provisions of this section shall be reviewed pursuant to Division 1.2 (commencing with Section 473). However, the review shall be limited to the fiscal feasibility and impact on the committee.

(g) This section shall become inoperative as of January 1, 2014.

~~SEC. 6.~~

SEC. 5. Section 1918 of the Business and Professions Code is amended to read:

1918. The committee shall license as a registered dental hygienist in extended functions a person who meets all of the following requirements:

(a) Holds a current license as a registered dental hygienist in California.

(b) Completes clinical training approved by the committee in a facility affiliated with a dental school under the direct supervision of the dental school faculty.

(c) Performs satisfactorily on an examination required by the committee.

(d) Completes an application form and pays all application fees required by the committee.

~~SEC. 7.~~

SEC. 6. Section 1922 of the Business and Professions Code is amended to read:

1922. The committee shall license as a registered dental hygienist in alternative practice a person who demonstrates satisfactory performance on an examination in California law and ethics required by the committee and who completes an application form and pays all application fees required by the committee and meets either of the following requirements:

(a) Holds a current California license as a registered dental hygienist and meets the following requirements:

(1) Has been engaged in the practice of dental hygiene, as defined in Section 1908, as a registered dental hygienist in any setting, including, but not limited to, educational settings and public health settings, for a minimum of 2,000 hours during the immediately preceding 36 months.

(2) Has successfully completed a bachelor's degree or its equivalent from a college or institution of higher education that is

accredited by a national or regional accrediting agency recognized by the United States Department of Education, and a minimum of 150 hours of additional educational requirements, as prescribed by the committee by regulation, that are consistent with good dental and dental hygiene practice, including, but not necessarily limited to, dental hygiene technique and theory including gerontology and medical emergencies, and business administration and practice management.

(b) Has received a letter of acceptance into the employment utilization phase of the Health Manpower Pilot Project No. 155 established by the Office of Statewide Health Planning and Development pursuant to Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code.

~~SEC. 8.~~

SEC. 7. Section 1927 of the Business and Professions Code is amended to read:

1927. A registered dental hygienist in alternative practice shall not do any of the following:

(a) Infer, purport, advertise, or imply that he or she is in any way able to provide dental services or make any type of dental diagnosis beyond evaluating a patient's dental hygiene status, providing a dental hygiene treatment plan, and providing the associated dental hygiene services.

(b) Hire a registered dental hygienist to provide direct patient services other than a registered dental hygienist in alternative practice.

~~SEC. 9.~~

SEC. 8. Section 1945 of the Business and Professions Code is repealed.

~~SEC. 10.~~

SEC. 9. Section 1950 of the Business and Professions Code is amended to read:

1950. (a) A licensee may have his or her license revoked or suspended, or may be reprimanded or placed on probation by the committee, for conviction of a crime substantially related to the licensee's qualifications, functions, or duties. The record of conviction or a copy certified by the clerk of the court or by the judge in whose court the conviction occurred shall be conclusive evidence of conviction.

(b) The committee shall undertake proceedings under this section upon the receipt of a certified copy of the record of conviction. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge of a felony or of any misdemeanor substantially related to the licensee's qualifications, functions, or duties is deemed to be a conviction within the meaning of this section.

(c) The committee may reprimand a licensee or order a license suspended or revoked, or placed on probation or may decline to issue a license, when any of the following occur:

(1) The time for appeal has elapsed.

(2) The judgment of conviction has been affirmed on appeal.

(3) An order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under any provision of the Penal Code, including, but not limited to, Section 1203.4 of the Penal Code, allowing a person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

~~SEC. 11.~~

SEC. 10. Section 1952 of the Business and Professions Code is amended to read:

1952. It is unprofessional conduct for a person licensed under this article to do any of the following:

(a) Obtain or possess in violation of law, or except as directed by a licensed physician and surgeon, dentist, or podiatrist, a controlled substance, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or any dangerous drug as defined in Section 4022.

(b) Use a controlled substance, as defined in Division 10 (commencing with Section 11000) of the Health and Safety Code, or a dangerous drug as defined in Section 4022, or alcoholic beverages or other intoxicating substances, to an extent or in a manner dangerous or injurious to himself or herself, to any person, or the public to the extent that the use impairs the licensee's ability to conduct with safety to the public the practice authorized by his or her license.

(c) Be convicted of a charge of violating any federal statute or rules, or any statute or rule of this state, regulating controlled substances, as defined in Division 10 (commencing with Section

11000) of the Health and Safety Code, or any dangerous drug, as defined in Section 4022, or be convicted of more than one misdemeanor, or any felony, involving the use or consumption of alcohol or drugs, if the conviction is substantially related to the practice authorized by his or her license.

(1) The record of conviction or a copy certified by the clerk of the court or by the judge in whose court the conviction is had, shall be conclusive evidence of a violation of this section. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this section.

(2) The committee may order the license suspended or revoked, or may decline to issue a license, when the time for appeal has elapsed or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending imposition of sentence, irrespective of a subsequent order under any provision of the Penal Code, including, but not limited to, Section 1203.4 of the Penal Code, allowing a person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

~~SEC. 12.~~

SEC. 11. Section 1955 of the Business and Professions Code is amended to read:

1955. (a) (1) A licensee who fails or refuses to comply with a request for a patient's dental or dental hygiene records that is accompanied by that patient's written authorization for release of the records to the committee, within 15 days of receiving the request and authorization, shall pay to the committee a civil or administrative penalty or fine up to a maximum of two hundred fifty dollars ($250) per day for each day that the documents have not been produced after the 15th day, up to a maximum of five thousand dollars ($5,000) unless the licensee is unable to provide the documents within this time period for good cause.

(2) A health care facility shall comply with a request for the dental or dental hygiene records of a patient that is accompanied by that patient's written authorization for release of records to the committee together with a notice citing this section and describing the penalties for failure to comply with this section. Failure to provide the authorizing patient's dental hygiene records to the committee within 30 days of receiving this request, authorization, and notice shall subject the health care facility to a civil or

administrative penalty or fine, payable to the committee, of up to a maximum of two hundred fifty dollars ($250) per day for each day that the documents have not been produced after the 30th day, up to a maximum of five thousand dollars ($5,000), unless the health care facility is unable to provide the documents within this time period for good cause. This paragraph shall not require health care facilities to assist the committee in obtaining the patient's authorization. The committee shall pay the reasonable cost of copying the dental hygiene records.

(b) (1) A licensee who fails or refuses to comply with a court order issued in the enforcement of a subpoena mandating the release of records to the committee shall pay to the committee a civil penalty of one thousand dollars ($1,000) per day for each day that the documents have not been produced after the date by which the court order requires the documents to be produced, unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the committee shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.

(2) A licensee who fails or refuses to comply with a court order issued in the enforcement of a subpoena mandating the release of records to the committee is guilty of a misdemeanor punishable by a fine payable to the committee not to exceed five thousand dollars ($5,000). The fine shall be added to the licensee's renewal fee if it is not paid by the next succeeding renewal date. Any statute of limitations applicable to the filing of an accusation by the committee shall be tolled during the period the licensee is out of compliance with the court order and during any related appeals.

(3) A health care facility that fails or refuses to comply with a court order issued in the enforcement of a subpoena mandating the release of patient records to the committee, that is accompanied by a notice citing this section and describing the penalties for failure to comply with this section, shall pay to the committee a civil penalty of up to one thousand dollars ($1,000) per day for each day that the documents have not been produced, up to ten thousand dollars ($10,000), after the date by which the court order requires the documents to be produced, unless it is determined that the order is unlawful or invalid. Any statute of limitations applicable to the filing of an accusation by the committee against a licensee shall be tolled during the period the health care facility

is out of compliance with the court order and during any related appeals.

(4) A health care facility that fails or refuses to comply with a court order, issued in the enforcement of a subpoena, mandating the release of records to the committee is guilty of a misdemeanor punishable by a fine payable to the committee not to exceed five thousand dollars ($5,000). Any statute of limitations applicable to the filing of an accusation by the committee against a licensee shall be tolled during the period the health care facility is out of compliance with the court order and during any related appeals.

(c) Multiple acts by a licensee in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars ($5,000) or by imprisonment in a county jail not exceeding six months, or by both that fine and imprisonment. Multiple acts by a health care facility in violation of subdivision (b) shall be punishable by a fine not to exceed five thousand dollars ($5,000) and shall be reported to the State Department of Public Health and shall be considered as grounds for disciplinary action with respect to licensure, including suspension or revocation of the license or permit.

(d) A failure or refusal to comply with a court order issued in the enforcement of a subpoena mandating the release of records to the committee constitutes unprofessional conduct and is grounds for suspension or revocation of his or her license.

(e) Imposition of the civil or administrative penalties authorized by this section shall be in accordance with the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Division 3 of Title 2 of the Government Code).

(f) For the purposes of this section, a "health care facility" means a clinic or health care facility licensed or exempt from licensure pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code.

~~SEC. 13.~~

SEC. 12. Section 1957 of the Business and Professions Code is amended to read:

1957. (a) A person whose license has been revoked or suspended, who has been placed on probation, or whose license was surrendered pursuant to a stipulated settlement as a condition to avoid a disciplinary administrative hearing, may petition the committee for reinstatement or modification of the penalty,

including modification or termination of probation, after a period of not less than the following minimum periods have elapsed from the effective date of the decision ordering disciplinary action:

(1) At least three years for reinstatement of a license revoked for unprofessional conduct or surrendered pursuant to a stipulated settlement as a condition to avoid an administrative disciplinary hearing.

(2) At least two years for early termination, or modification of a condition, of a probation of three years or more.

(3) At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination, or modification of a condition, of a probation of less than three years.

(b) The petition shall state any fact required by the committee.

(c) The petition may be heard by the committee, or the committee may assign the petition to an administrative law judge designated in Section 11371 of the Government Code.

(d) In considering reinstatement or modification or penalty, the committee or the administrative law judge hearing the petition may consider the following:

(1) All activities of the petitioner since the disciplinary action was taken.

(2) The offense for which the petitioner was disciplined.

(3) The petitioner's activities during the time the license or permit was in good standing.

(4) The petitioner's rehabilitative efforts, general reputation for truth, and professional ability.

(e) The hearing may be continued from time to time as the committee or the administrative law judge as designated in Section 11371 of the Government Code finds necessary.

(f) The committee or the administrative law judge may impose necessary terms and conditions on the licentiate in reinstating a license or permit or modifying a penalty.

(g) A petition shall not be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole.

(h) A petition shall not be considered while there is an accusation or petition to revoke probation pending against the person.

(i) The committee may deny without a hearing or argument any petition filed pursuant to this section within a period of two years from the effective date of the prior decision following a hearing under this section. Nothing in this section shall be deemed to alter Sections 822 and 823.

~~SEC. 14.~~

SEC. 13. Section 1959 of the Business and Professions Code is amended to read:

1959. A person who holds a valid, unrevoked, and unsuspended license as a registered dental hygienist, registered dental hygienist in alternative practice, or registered dental hygienist in extended functions under this article may append the letters "R.D.H.," "R.D.H.A.P.," or "R.D.H.E.F.," respectively, to his or her name.

~~SEC. 15.~~

SEC. 14. Section 1961 of the Business and Professions Code is amended to read:

1961. A person who willfully, under circumstances that cause risk of bodily harm, serious physical or mental illness, or death, practices, attempts to practice, advertises, or holds himself or herself out as practicing dental hygiene without having at the time of so doing a valid, unrevoked, and unsuspended license as provided in this article, is guilty of a crime, punishable by imprisonment in a county jail for up to one year. The remedy provided in this section shall not preclude any other remedy provided by law.

~~SEC. 16.~~

SEC. 15. Section 1962 of the Business and Professions Code is amended to read:

1962. (a) An association, partnership, corporation, or group of three or more registered dental hygienists in alternative practice engaging in practice under a name that would otherwise be in violation of Section 1960 may practice under that name if the association, partnership, corporation, or group holds an unexpired, unsuspended, and unrevoked permit issued by the committee under this section.

(b) An individual registered dental hygienist in alternative practice or a pair of registered dental hygienists in alternative practice who practice dental hygiene under a name that would otherwise violate Section 1960 may practice under that name if the licensees hold a valid permit issued by the committee under

this section. The committee shall issue a written permit authorizing the holder to use a name specified in the permit in connection with the holder's practice if the committee finds all of the following:

(1) The applicant or applicants are duly licensed registered dental hygienists in alternative practice.

(2) The place where the applicant or applicants practice is owned or leased by the applicant or applicants, and the practice conducted at the place is wholly owned and entirely controlled by the applicant or applicants and is an approved area or practice setting pursuant to Section 1926.

(3) The name under which the applicant or applicants propose to operate contains at least one of the following designations: "dental hygiene group," "dental hygiene practice," or "dental hygiene office," contains the family name of one or more of the past, present, or prospective associates, partners, shareholders, or members of the group, and is in conformity with Section 651 and not in violation of subdivisions (i) and (*l*) of Section 1950.5.

(4) All licensed persons practicing at the location designated in the application hold valid licenses and no charges of unprofessional conduct are pending against any person practicing at that location.

(c) A permit issued under this section shall expire and become invalid unless renewed in the manner provided for in this article for the renewal of permits issued under this article.

(d) A permit issued under this section may be revoked or suspended if the committee finds that any requirement for original issuance of a permit is no longer being fulfilled by the permitholder. Proceedings for revocation or suspension shall be governed by the Administrative Procedure Act.

(e) If charges of unprofessional conduct are filed against the holder of a permit issued under this section, or a member of an association, partnership, group, or corporation to whom a permit has been issued under this section, proceedings shall not be commenced for revocation or suspension of the permit until a final determination of the charges of unprofessional conduct, unless the charges have resulted in revocation or suspension of a license.

~~SEC. 17.~~

SEC. 16. Section 1963 of the Business and Professions Code is amended to read:

1963. The committee may file a complaint for violation of any part of this article with any court of competent jurisdiction and

may, by its officers, counsel and agents, assist in presenting the law or facts at the trial. The district attorney of each county in this state shall prosecute all violations of this article in their respective counties in which the violations occur.

~~SEC. 18.~~

SEC. 17. Section 1966.1 of the Business and Professions Code is amended to read:

1966.1. (a) The committee shall establish criteria for the acceptance, denial, or termination of licensees in a diversion program. Unless ordered by the committee as a condition of a licensee's disciplinary probation, only those licensees who have voluntarily requested diversion treatment and supervision by a diversion evaluation committee shall participate in a diversion program.

(b) A licensee who is not the subject of a current investigation may self-refer to the diversion program on a confidential basis, except as provided in subdivision (f).

(c) A licensee under current investigation by the committee may also request entry into a diversion program by contacting the committee. The committee may refer the licensee requesting participation in the program to a diversion evaluation committee for evaluation of eligibility. Prior to authorizing a licensee to enter into the diversion program, the committee may require the licensee, while under current investigation for any violations of this article or other violations, to execute a statement of understanding that states that the licensee understands that his or her violations of this article or other statutes, that would otherwise be the basis for discipline, may still be investigated and the subject of disciplinary action.

(d) If the reasons for a current investigation of a licensee are based primarily on the self-administration of any controlled substance or dangerous drugs or alcohol under Section 1951, or the illegal possession, prescription, or nonviolent procurement of any controlled substance or dangerous drugs for self-administration that does not involve actual, direct harm to the public, the committee shall close the investigation without further action if the licensee is accepted into the committee's diversion program and successfully completes the requirements of the program. If the licensee withdraws or is terminated from the program by a diversion evaluation committee, the investigation shall be reopened

and disciplinary action imposed, if warranted, as determined by the committee.

(e) Neither acceptance nor participation in the diversion program shall preclude the committee from investigating or continuing to investigate, or taking disciplinary action or continuing to take disciplinary action against, any licensee for any unprofessional conduct committed before, during, or after participation in the diversion program.

(f) All licensees shall sign an agreement of understanding that the withdrawal or termination from the diversion program at a time when a diversion evaluation committee determines the licensee presents a threat to the public's health and safety shall result in the utilization by the committee of diversion treatment records in disciplinary or criminal proceedings.

(g) Any licensee terminated from the diversion program for failure to comply with program requirements is subject to disciplinary action by the committee for acts committed before, during, and after participation in the diversion program. A licensee who has been under investigation by the committee and has been terminated from the diversion program by a diversion evaluation committee shall be reported by the diversion evaluation committee to the committee.

~~SEC. 19.~~

SEC. 18. Section 2736.5 of the Business and Professions Code is amended to read:

2736.5. (a) Any person who has served on active duty in the medical corps of any of the Armed Forces of the United States and who has successfully completed the course of instruction required to qualify him or her for rating as a medical service technician—independent duty, or other equivalent rating in his particular branch of the Armed Forces, and whose service in the Armed Forces has been under honorable conditions, may submit the record of such training to the board for evaluation.

(b) If such person meets the qualifications of paragraphs (1) and (3) of subdivision (a) of Section 2736, and if the board determines that his or her education would give reasonable assurance of competence to practice as a registered nurse in this state, he or she shall be granted a license upon passing the standard examination for such licensure.

(c) The board shall, by regulation, establish criteria for evaluating the education of applicants under this section.

(d) The board shall maintain records of the following categories of applicants under this section:

(1) Applicants who are rejected for examination, and the areas of such applicants' preparation which are the causes of rejection.

(2) Applicants who are qualified by their military education alone to take the examination, and the results of their examinations.

(3) Applicants who are qualified to take the examination by their military education plus supplementary education, and the results of their examinations.

(e) The board shall attempt to contact by mail or other means individuals meeting the requirements of subdivision (a) who have been or will be discharged or separated from the Armed Forces of the United States, in order to inform them of the application procedure provided by this section. The board may enter into an agreement with the federal government in order to secure the names and addresses of such individuals.

~~SEC. 20.~~

SEC. 19. Section 2836.2 of the Business and Professions Code is amended to read:

2836.2. Furnishing or ordering of drugs or devices by nurse practitioners is defined to mean the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure. All nurse practitioners who are authorized pursuant to Section 2836.1 to furnish or issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration.

~~SEC. 21.~~

SEC. 20. Section 2936 of the Business and Professions Code is amended to read:

2936. The board shall adopt a program of consumer and professional education in matters relevant to the ethical practice of psychology. The board shall establish as its standards of ethical conduct relating to the practice of psychology, the "Ethical Principles and Code of Conduct" published by the American Psychological Association (APA). Those standards shall be applied by the board as the accepted standard of care in all licensing examination development and in all board enforcement policies and disciplinary case evaluations.

To facilitate consumers in receiving appropriate psychological services, all licensees and registrants shall be required to post, in a conspicuous location in their principal psychological business office, a notice which reads as follows:

"NOTICE TO CONSUMERS: The Department of Consumer Affair's Board of Psychology receives and responds to questions and complaints regarding the practice of psychology. If you have questions or complaints, you may contact the board on the Internet at www.psychboard.ca.gov, by calling 1-866-503-3221, or by writing to the following address:
Board of Psychology
2005 Evergreen Street, Suite 1400
Sacramento, California 95815-3894"

~~SEC. 22.~~

SEC. 21. Section 3519 of the Business and Professions Code is amended to read:

3519. The committee shall issue under the name of the Medical Board of California a license to all physician assistant applicants who meet all of the following requirements:

(a) Provide evidence of successful completion of an approved program.

(b) Pass any examination required under Section 3517.

(c) Not be subject to denial of licensure under Division 1.5 (commencing with Section 475) or Section 3527.

(d) Pay all fees required under Section 3521.1.

~~SEC. 23.~~

SEC. 22. Section 3575 of the Business and Professions Code is amended to read:

3575. (a) For the purposes of this chapter, the following definitions shall apply:

(1) "Board" means the Medical Board of California.

(2) "Polysomnography" means the treatment, management, diagnostic testing, control, education, and care of patients with sleep and wake disorders. Polysomnography shall include, but not be limited to, the process of analysis, monitoring, and recording of physiologic data during sleep and wakefulness to assist in the treatment of disorders, syndromes, and dysfunctions that are sleep-related, manifest during sleep, or disrupt normal sleep

activities. Polysomnography shall also include, but not be limited to, the therapeutic and diagnostic use of oxygen, the use of positive airway pressure including continuous positive airway pressure (CPAP) and bilevel modalities, adaptive servo-ventilation, and maintenance of nasal and oral airways that do not extend into the trachea.

(3) "Supervision" means that the supervising physician and surgeon shall remain available, either in person or through telephonic or electronic means, at the time that the polysomnographic services are provided.

(b) (1) Within one year after the effective date of this chapter, the board shall promulgate regulations relative to the qualifications for the registration of individuals as certified polysomnographic technologists, polysomnographic technicians, and polysomnographic trainees. The qualifications for a certified polysomnographic technologist shall include all of the following:

(A) He or she shall have valid, current credentials as a polysomnographic technologist issued by a national accrediting agency approved by the board.

(B) He or she shall have graduated from a polysomnographic educational program that has been approved by the board.

(C) He or she shall have passed a national certifying examination that has been approved by the board.

(2) An applicant for registration as a certified polysomnographic technologist may satisfy the qualifications described in paragraph (1) by submitting proof to the board that he or she has been practicing polysomnography for at least five years in a manner that is acceptable to the board. However, beginning three years after the effective date of this chapter, all individuals seeking to obtain certification as a polysomnographic technologist shall have passed a national certifying examination that has been approved by the board.

(c) In accordance with Section 144, any person seeking registration from the board as a certified polysomnographic technologist, a polysomnographic technician, or a polysomnographic trainee shall be subject to a state and federal level criminal offender record information search conducted through the Department of Justice as specified in paragraphs (1) to (5), inclusive, of this subdivision.

(1) The board shall submit to the Department of Justice fingerprint images and related information required by the Department of Justice of all polysomnographic technologist, technician, or trainee certification candidates for the purposes of obtaining information as to the existence and content of a record of state or federal convictions and state or federal arrests and also information as to the existence and content of a record of state or federal arrests for which the Department of Justice establishes that the person is free on bail or on his or her recognizance pending trial or appeal.

(2) When received, the Department of Justice shall forward to the Federal Bureau of Investigation requests for federal summary criminal history information received pursuant to this subdivision. The Department of Justice shall review the information returned from the Federal Bureau of Investigation and compile and disseminate a response to the board.

(3) The Department of Justice shall provide state and federal responses to the board pursuant to paragraph (1) of subdivision (p) of Section 11105 of the Penal Code.

(4) The board shall request from the Department of Justice subsequent arrest notification service, pursuant to Section 11105.2 of the Penal Code, for persons described in this subdivision.

(5) The Department of Justice shall charge a fee sufficient to cover the cost of processing the request described in this subdivision. The individual seeking registration shall be responsible for this cost.

(d) An individual may use the title "certified polysomnographic technologist" and may engage in the practice of polysomnography only under the following circumstances:

(1) He or she is registered with the board and has successfully undergone a state and federal level criminal offender record information search pursuant to subdivision (c).

(2) He or she works under the supervision and direction of a licensed physician and surgeon.

(3) He or she meets the requirements of this chapter.

(e) Within one year after the effective date of this chapter, the board shall adopt regulations that establish the means and circumstances in which a licensed physician and surgeon may employ polysomnographic technicians and polysomnographic trainees. The board may also adopt regulations specifying the scope

of services that may be provided by a polysomnographic technician or polysomnographic trainee. Any regulation adopted pursuant to this section may specify the level of supervision that polysomnographic technicians and trainees are required to have when working under the supervision of a certified polysomnographic technologist or licensed health care professional.

(f) This section shall not apply to California licensed allied health professionals, including, but not limited to, respiratory care practitioners, working within the scope of practice of their license.

(g) Nothing in this chapter shall be interpreted to authorize a polysomnographic technologist, technician, or trainee to treat, manage, control, educate, or care for patients other than those with sleep disorders or to provide diagnostic testing for patients other than those with suspected sleep disorders.

~~SEC. 24.~~

SEC. 23. Section 4200 of the Business and Professions Code is amended to read:

4200. (a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall

be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

~~SEC. 25.~~

SEC. 24. Section 4836.1 of the Business and Professions Code is amended to read:

4836.1. (a) Notwithstanding any other provision of law, a registered veterinary technician or an unregistered assistant may administer a drug, including, but not limited to, a drug that is a controlled substance, under the direct or indirect supervision of a licensed veterinarian when done pursuant to the order, control, and full professional responsibility of a licensed veterinarian. However, no person, other than a licensed veterinarian, may induce anesthesia unless authorized by regulation of the board.

(b) For purposes of this section, the following definitions apply:

(1) "Controlled substance" has the same meaning as that term is defined in Section 11007 of the Health and Safety Code.

(2) "Direct supervision" has the same meaning as that term is defined in subdivision (e) of Section 2034 of Title 16 of the California Code of Regulations.

(3) "Drug" has the same meaning as that term is defined in Section 11014 of the Health and Safety Code.

(4) "Indirect supervision" has the same meaning as that term is defined in subdivision (f) of Section 2034 of Title 16 of the California Code of Regulations.

(c) This section shall remain in effect until January 1, 2013, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 2013, deletes or extends that date.

~~SEC. 26.~~

SEC. 25. Section 4980.36 of the Business and Professions Code is amended to read:

4980.36. (a) This section shall apply to the following:

(1) Applicants for licensure or registration who begin graduate study before August 1, 2012, and do not complete that study on or before December 31, 2018.

(2) Applicants for licensure or registration who begin graduate study before August 1, 2012, and who graduate from a degree program that meets the requirements of this section.

(3) Applicants for licensure or registration who begin graduate study on or after August 1, 2012.

(b) To qualify for a license or registration, applicants shall possess a doctor's or master's degree meeting the requirements of this section in marriage, family, and child counseling, marriage and family therapy, couple and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling or marriage and family therapy, obtained from a school, college, or university approved by the Bureau for Private Postsecondary Education or accredited by either the Commission on the Accreditation of Marriage and Family Therapy Education or a regional accrediting agency recognized by the United States Department of Education. The board has the authority to make the final determination as to whether a degree meets all requirements, including, but not limited to, course requirements, regardless of accreditation or approval.

(c) A doctor's or master's degree program that qualifies for licensure or registration shall do the following:

(1) Integrate all of the following throughout its curriculum:

(A) Marriage and family therapy principles.

(B) The principles of mental health recovery-oriented care and methods of service delivery in recovery-oriented practice environments, among others.

(C) An understanding of various cultures and the social and psychological implications of socioeconomic position, and an understanding of how poverty and social stress impact an individual's mental health and recovery.

(2) Allow for innovation and individuality in the education of marriage and family therapists.

(3) Encourage students to develop the personal qualities that are intimately related to effective practice, including, but not limited to, integrity, sensitivity, flexibility, insight, compassion, and personal presence.

(4) Permit an emphasis or specialization that may address any one or more of the unique and complex array of human problems,

symptoms, and needs of Californians served by marriage and family therapists.

(5) Provide students with the opportunity to meet with various consumers and family members of consumers of mental health services to enhance understanding of their experience of mental illness, treatment, and recovery.

(d) The degree described in subdivision (b) shall contain no less than 60 semester or 90 quarter units of instruction that includes, but is not limited to, the following requirements:

(1) Both of the following:

(A) No less than 12 semester or 18 quarter units of coursework in theories, principles, and methods of a variety of psychotherapeutic orientations directly related to marriage and family therapy and marital and family systems approaches to treatment and how these theories can be applied therapeutically with individuals, couples, families, adults, including elder adults, children, adolescents, and groups to improve, restore, or maintain healthy relationships.

(B) Practicum that involves direct client contact, as follows:

(i) A minimum of six semester or nine quarter units of practicum in a supervised clinical placement that provides supervised fieldwork experience.

(ii) A minimum of 150 hours of face-to-face experience counseling individuals, couples, families, or groups.

(iii) A student must be enrolled in a practicum course while counseling clients.

(iv) The practicum shall provide training in all of the following areas:

(I) Applied use of theory and psychotherapeutic techniques.

(II) Assessment, diagnosis, and prognosis.

(III) Treatment of individuals and premarital, couple, family, and child relationships, including trauma and abuse, dysfunctions, healthy functioning, health promotion, illness prevention, and working with families.

(IV) Professional writing, including documentation of services, treatment plans, and progress notes.

(V) How to connect people with resources that deliver the quality of services and support needed in the community.

(v) Educational institutions are encouraged to design the practicum required by this subparagraph to include marriage and

family therapy experience in low-income and multicultural mental health settings.

(vi) In addition to the 150 hours required in clause (ii), 75 hours of either of the following:

(I) Client-centered advocacy, as defined in Section 4980.03.

(II) Face-to-face experience counseling individuals, couples, families, or groups.

(2) Instruction in all of the following:

(A) Diagnosis, assessment, prognosis, and treatment of mental disorders, including severe mental disorders, evidence-based practices, psychological testing, psychopharmacology, and promising mental health practices that are evaluated in peer reviewed literature.

(B) Developmental issues from infancy to old age, including instruction in all of the following areas:

(i) The effects of developmental issues on individuals, couples, and family relationships.

(ii) The psychological, psychotherapeutic, and health implications of developmental issues and their effects.

(iii) Aging and its biological, social, cognitive, and psychological aspects.

(iv) A variety of cultural understandings of human development.

(v) The understanding of human behavior within the social context of socioeconomic status and other contextual issues affecting social position.

(vi) The understanding of human behavior within the social context of a representative variety of the cultures found within California.

(vii) The understanding of the impact that personal and social insecurity, social stress, low educational levels, inadequate housing, and malnutrition have on human development.

(C) The broad range of matters and life events that may arise within marriage and family relationships and within a variety of California cultures, including instruction in all of the following:

(i) Child and adult abuse assessment and reporting.

(ii) Spousal or partner abuse assessment, detection, intervention strategies, and same-gender abuse dynamics.

(iii) Cultural factors relevant to abuse of partners and family members.

(iv) Childbirth, child rearing, parenting, and stepparenting.

(v) Marriage, divorce, and blended families.

(vi) Long-term care.

(vii) End of life and grief.

(viii) Poverty and deprivation.

(ix) Financial and social stress.

(x) Effects of trauma.

(xi) The psychological, psychotherapeutic, community, and health implications of the matters and life events described in clauses (i) to (x), inclusive.

(D) Cultural competency and sensitivity, including a familiarity with the racial, cultural, linguistic, and ethnic backgrounds of persons living in California.

(E) Multicultural development and cross-cultural interaction, including experiences of race, ethnicity, class, spirituality, sexual orientation, gender, and disability, and their incorporation into the psychotherapeutic process.

(F) The effects of socioeconomic status on treatment and available resources.

(G) Resilience, including the personal and community qualities that enable persons to cope with adversity, trauma, tragedy, threats, or other stresses.

(H) Human sexuality, including the study of physiological, psychological, and social cultural variables associated with sexual behavior and gender identity, and the assessment and treatment of psychosexual dysfunction.

(I) Substance use disorders, co-occurring disorders, and addiction, including, but not limited to, instruction in all of the following:

(i) The definition of substance use disorders, co-occurring disorders, and addiction. For purposes of this subparagraph, “co-occurring disorders” means a mental illness and substance abuse diagnosis occurring simultaneously in an individual.

(ii) Medical aspects of substance use disorders and co-occurring disorders.

(iii) The effects of psychoactive drug use.

(iv) Current theories of the etiology of substance abuse and addiction.

(v) The role of persons and systems that support or compound substance abuse and addiction.

(vi) Major approaches to identification, evaluation, and treatment of substance use disorders, co-occurring disorders, and addiction, including, but not limited to, best practices.

(vii) Legal aspects of substance abuse.

(viii) Populations at risk with regard to substance use disorders and co-occurring disorders.

(ix) Community resources offering screening, assessment, treatment, and followup for the affected person and family.

(x) Recognition of substance use disorders, co-occurring disorders, and addiction, and appropriate referral.

(xi) The prevention of substance use disorders and addiction.

(J) California law and professional ethics for marriage and family therapists, including instruction in all of the following areas of study:

(i) Contemporary professional ethics and statutory, regulatory, and decisional laws that delineate the scope of practice of marriage and family therapy.

(ii) The therapeutic, clinical, and practical considerations involved in the legal and ethical practice of marriage and family therapy, including, but not limited to, family law.

(iii) The current legal patterns and trends in the mental health professions.

(iv) The psychotherapist-patient privilege, confidentiality, the patient dangerous to self or others, and the treatment of minors with and without parental consent.

(v) A recognition and exploration of the relationship between a practitioner's sense of self and human values and his or her professional behavior and ethics.

(vi) Differences in legal and ethical standards for different types of work settings.

(vii) Licensing law and licensing process.

(e) The degree described in subdivision (b) shall, in addition to meeting the requirements of subdivision (d), include instruction in case management, systems of care for the severely mentally ill, public and private services and supports available for the severely mentally ill, community resources for persons with mental illness and for victims of abuse, disaster and trauma response, advocacy for the severely mentally ill, and collaborative treatment. This instruction may be provided either in credit level coursework or

through extension programs offered by the degree-granting institution.

(f) The changes made to law by this section are intended to improve the educational qualifications for licensure in order to better prepare future licentiates for practice, and are not intended to expand or restrict the scope of practice for marriage and family therapists.

~~SEC. 27.~~

SEC. 26. Section 4980.37 of the Business and Professions Code is amended to read:

4980.37. (a) This section shall apply to applicants for licensure or registration who begin graduate study before August 1, 2012, and complete that study on or before December 31, 2018. Those applicants may alternatively qualify under paragraph (2) of subdivision (a) of Section 4980.36.

(b) To qualify for a license or registration, applicants shall possess a doctor's or master's degree in marriage, family, and child counseling, marriage and family therapy, couple and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling or marriage and family therapy, obtained from a school, college, or university accredited by a regional accrediting agency recognized by the United States Department of Education or approved by the Bureau for Private Postsecondary Education. The board has the authority to make the final determination as to whether a degree meets all requirements, including, but not limited to, course requirements, regardless of accreditation or approval. In order to qualify for licensure pursuant to this section, a doctor's or master's degree program shall be a single, integrated program primarily designed to train marriage and family therapists and shall contain no less than 48 semester or 72 quarter units of instruction. This instruction shall include no less than 12 semester units or 18 quarter units of coursework in the areas of marriage, family, and child counseling, and marital and family systems approaches to treatment. The coursework shall include all of the following areas:

(1) The salient theories of a variety of psychotherapeutic orientations directly related to marriage and family therapy, and marital and family systems approaches to treatment.

(2) Theories of marriage and family therapy and how they can be utilized in order to intervene therapeutically with couples, families, adults, children, and groups.

(3) Developmental issues and life events from infancy to old age and their effect on individuals, couples, and family relationships. This may include coursework that focuses on specific family life events and the psychological, psychotherapeutic, and health implications that arise within couples and families, including, but not limited to, childbirth, child rearing, childhood, adolescence, adulthood, marriage, divorce, blended families, stepparenting, abuse and neglect of older and dependent adults, and geropsychology.

(4) A variety of approaches to the treatment of children.

The board shall, by regulation, set forth the subjects of instruction required in this subdivision.

(c) (1) In addition to the 12 semester or 18 quarter units of coursework specified in subdivision (b), the doctor's or master's degree program shall contain not less than six semester or nine quarter units of supervised practicum in applied psychotherapeutic technique, assessments, diagnosis, prognosis, and treatment of premarital, couple, family, and child relationships, including dysfunctions, healthy functioning, health promotion, and illness prevention, in a supervised clinical placement that provides supervised fieldwork experience within the scope of practice of a marriage and family therapist.

(2) For applicants who enrolled in a degree program on or after January 1, 1995, the practicum shall include a minimum of 150 hours of face-to-face experience counseling individuals, couples, families, or groups.

(3) The practicum hours shall be considered as part of the 48 semester or 72 quarter unit requirement.

(d) As an alternative to meeting the qualifications specified in subdivision (b), the board shall accept as equivalent degrees those master's or doctor's degrees granted by educational institutions whose degree program is approved by the Commission on Accreditation for Marriage and Family Therapy Education.

(e) In order to provide an integrated course of study and appropriate professional training, while allowing for innovation and individuality in the education of marriage and family therapists, a degree program that meets the educational qualifications for

licensure or registration under this section shall do all of the following:

(1) Provide an integrated course of study that trains students generally in the diagnosis, assessment, prognosis, and treatment of mental disorders.

(2) Prepare students to be familiar with the broad range of matters that may arise within marriage and family relationships.

(3) Train students specifically in the application of marriage and family relationship counseling principles and methods.

(4) Encourage students to develop those personal qualities that are intimately related to the counseling situation such as integrity, sensitivity, flexibility, insight, compassion, and personal presence.

(5) Teach students a variety of effective psychotherapeutic techniques and modalities that may be utilized to improve, restore, or maintain healthy individual, couple, and family relationships.

(6) Permit an emphasis or specialization that may address any one or more of the unique and complex array of human problems, symptoms, and needs of Californians served by marriage and family therapists.

(7) Prepare students to be familiar with cross-cultural mores and values, including a familiarity with the wide range of racial and ethnic backgrounds common among California's population, including, but not limited to, Blacks, Hispanics, Asians, and Native Americans.

(f) Educational institutions are encouraged to design the practicum required by this section to include marriage and family therapy experience in low-income and multicultural mental health settings.

(g) This section shall remain in effect only until January 1, 2019, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2019, deletes or extends that date.

~~SEC. 28.~~

SEC. 27. Section 4980.40.5 of the Business and Professions Code is amended to read:

4980.40.5. (a) A doctoral or master's degree in marriage, family, and child counseling, marital and family therapy, couple and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling, or marriage and family therapy, obtained from a school, college, or university approved by the

Bureau for Private Postsecondary Education as of June 30, 2007, shall be considered by the board to meet the requirements necessary for licensure as a marriage and family therapist and for registration as a marriage and family therapist intern provided that the degree is conferred on or before July 1, 2010.

(b) As an alternative to meeting the qualifications specified in subdivision (a) of Section 4980.40, the board shall accept as equivalent degrees those doctoral or master's degrees that otherwise meet the requirements of this chapter and are conferred by educational institutions accredited by any of the following associations:

(1) Northwest Commission on Colleges and Universities.

(2) Middle States Association of Colleges and Secondary Schools.

(3) New England Association of Schools and Colleges.

(4) North Central Association of Colleges and Secondary Schools.

(5) Southern Association of Colleges and Schools.

~~SEC. 29.~~

SEC. 28. Section 4980.42 of the Business and Professions Code is amended to read:

4980.42. (a) Trainees performing services in any work setting specified in subdivision (d) of Section 4980.43 may perform those activities and services as a trainee, provided that the activities and services constitute part of the trainee's supervised course of study and that the person is designated by the title "trainee." Trainees may gain hours of experience outside the required practicum. Those hours shall be subject to the requirements of subdivision (b) and to the other requirements of this chapter.

(b) On and after January 1, 1995, all hours of experience gained as a trainee shall be coordinated between the school and the site where the hours are being accrued. The school shall approve each site and shall have a written agreement with each site that details each party's responsibilities, including the methods by which supervision shall be provided. The agreement shall provide for regular progress reports and evaluations of the student's performance at the site. If an applicant has gained hours of experience while enrolled in an institution other than the one that confers the qualifying degree, it shall be the applicant's responsibility to provide to the board satisfactory evidence that

those hours of trainee experience were gained in compliance with this section.

~~SEC. 30.~~

SEC. 29. Section 4980.45 of the Business and Professions Code is amended to read:

4980.45. (a) A licensed professional in private practice who has satisfied the requirements of subdivision (g) of Section 4980.03 may supervise or employ, at any one time, no more than a total of three individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker in that private practice.

(b) A marriage and family therapy corporation may employ, at any one time, no more than a total of three individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker for each employee or shareholder who has satisfied the requirements of subdivision (g) of Section 4980.03. In no event shall any marriage and family therapy corporation employ, at any one time, more than a total of 15 individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. In no event shall any supervisor supervise, at any one time, more than a total of three individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. Persons who supervise individuals registered as either a marriage and family therapist intern or associate clinical social worker shall be employed full time by the marriage and family therapy corporation and shall be actively engaged in performing professional services at and for the marriage and family therapy corporation. Employment and supervision within a marriage and family therapy corporation shall be subject to all laws and regulations governing experience and supervision gained in a private practice setting.

~~SEC. 31.~~

SEC. 30. Section 4982.25 of the Business and Professions Code is amended to read:

4982.25. The board may deny an application, or may suspend or revoke a license or registration issued under this chapter, for any of the following:

(a) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory

or possession of the United States, or by any other governmental agency, on a license, certificate, or registration to practice marriage and family therapy, or any other healing art, shall constitute unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

(b) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a marriage and family therapist, clinical social worker, professional clinical counselor, or educational psychologist shall also constitute grounds for disciplinary action for unprofessional conduct against the licensee or registrant under this chapter.

~~SEC. 32.~~

SEC. 31. Section 4989.54 of the Business and Professions Code is amended to read:

4989.54. The board may deny a license or may suspend or revoke the license of a licensee if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) Conviction of a crime substantially related to the qualifications, functions, and duties of an educational psychologist.

(1) The record of conviction shall be conclusive evidence only of the fact that the conviction occurred.

(2) The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee under this chapter.

(3) A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee under this chapter shall be deemed to be a conviction within the meaning of this section.

(4) The board may order a license suspended or revoked, or may decline to issue a license when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty or setting aside the verdict of guilty or dismissing the accusation, information, or indictment.

(b) Securing a license by fraud, deceit, or misrepresentation on an application for licensure submitted to the board, whether engaged in by an applicant for a license or by a licensee in support of an application for licensure.

(c) Administering to himself or herself a controlled substance or using any of the dangerous drugs specified in Section 4022 or an alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to himself or herself or to any other person or to the public or to the extent that the use impairs his or her ability to safely perform the functions authorized by the license. The board shall deny an application for a license or revoke the license of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing educational psychology.

(d) Failure to comply with the consent provisions in Section 2290.5.

(e) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(f) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(g) Commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee.

(h) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory or possession of the United States or by any other governmental agency, on a license, certificate, or registration to practice educational psychology or any other healing art. A certified copy of the disciplinary action, decision, or judgment shall be conclusive evidence of that action.

(i) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as an educational psychologist, a clinical social worker, professional clinical counselor, or marriage and family therapist.

(j) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(k) Gross negligence or incompetence in the practice of educational psychology.

(*l*) Misrepresentation as to the type or status of a license held by the licensee or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(m) Intentionally or recklessly causing physical or emotional harm to any client.

(n) Engaging in sexual relations with a client or a former client within two years following termination of professional services, soliciting sexual relations with a client, or committing an act of sexual abuse or sexual misconduct with a client or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed educational psychologist.

(o) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services or the basis upon which that fee will be computed.

(p) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients.

(q) Failing to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(r) Performing, holding himself or herself out as being able to perform, or offering to perform any professional services beyond the scope of the license authorized by this chapter or beyond his or her field or fields of competence as established by his or her education, training, or experience.

(s) Reproducing or describing in public, or in any publication subject to general public distribution, any psychological test or other assessment device the value of which depends in whole or in part on the naivete of the subject in ways that might invalidate the test or device. An educational psychologist shall limit access to the test or device to persons with professional interests who can be expected to safeguard its use.

(t) Aiding or abetting an unlicensed person to engage in conduct requiring a license under this chapter.

(u) When employed by another person or agency, encouraging, either orally or in writing, the employer's or agency's clientele to utilize his or her private practice for further counseling without the approval of the employing agency or administration.

(v) Failing to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(w) Failing to comply with the elder and adult dependent abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(x) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(y) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(z) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of the examination as described in Section 123.

(aa) Impersonation of another by any licensee or applicant for a license, or, in the case of a licensee, allowing any other person to use his or her license.

(ab) Permitting a person under his or her supervision or control to perform, or permitting that person to hold himself or herself out as competent to perform, professional services beyond the level of education, training, or experience of that person.

~~SEC. 33.~~

SEC. 32. Section 4990.38 of the Business and Professions Code is amended to read:

4990.38. The board may deny an application or may suspend or revoke a license or registration issued under the chapters it administers and enforces for any disciplinary action imposed by this state or another state or territory or possession of the United States, or by a governmental agency on a license, certificate or registration to practice marriage and family therapy, clinical social work, educational psychology, professional clinical counseling, or any other healing art. The disciplinary action, which may include denial of licensure or revocation or suspension of the license or imposition of restrictions on it, constitutes unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

~~SEC. 34.~~

SEC. 33. Section 4992.3 of the Business and Professions Code is amended to read:

4992.3. The board may deny a license or a registration, or may suspend or revoke the license or registration of a licensee or registrant if he or she has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter is a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the

verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022 or any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license. The board shall deny an application for a registration or license or revoke the license or registration of any person who uses or offers to use drugs in the course of performing clinical social work. This provision does not apply to any person also licensed as a physician and surgeon under Chapter 5 (commencing with Section 2000) or the Osteopathic Act who lawfully prescribes drugs to a patient under his or her care.

(d) Incompetence in the performance of clinical social work.

(e) An act or omission that falls sufficiently below the standard of conduct of the profession as to constitute an act of gross negligence.

(f) Violating, attempting to violate, or conspiring to violate this chapter or any regulation adopted by the board.

(g) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity. For purposes of this subdivision, this misrepresentation includes, but is not limited to, misrepresentation of the person's qualifications as an adoption service provider pursuant to Section 8502 of the Family Code.

(h) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee, allowing any other person to use his or her license or registration.

(i) Aiding or abetting any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(j) Intentionally or recklessly causing physical or emotional harm to any client.

(k) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(*l*) Engaging in sexual relations with a client or with a former client within two years from the termination date of therapy with the client, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a clinical social worker.

(m) Performing, or holding one's self out as being able to perform, or offering to perform or permitting, any registered associate clinical social worker or intern under supervision to perform any professional services beyond the scope of one's competence, as established by one's education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(n) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client that is obtained from tests or other means.

(o) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(p) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (o).

(q) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(r) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device. A licensee shall limit access to that test or device to persons with professional interest who are expected to safeguard its use.

(s) Any conduct in the supervision of any registered associate clinical social worker, intern, or trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(t) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(u) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(v) Failure to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(w) Willful violation of Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(x) Failure to comply with Section 2290.5.

(y) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(z) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of the examination as described in Section 123.

~~SEC. 35.~~

SEC. 34. Section 4992.36 of the Business and Professions Code is amended to read:

4992.36. The board may deny an application, or may suspend or revoke a license or registration issued under this chapter, for any of the following:

(a) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by another state or territory of the United States, or by any other governmental agency, on a license, certificate, or registration to practice clinical social work or any other healing art shall constitute grounds for disciplinary action for unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

(b) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice clinical social work, marriage and family therapy, professional clinical counseling, or educational psychology against a licensee or registrant shall also constitute grounds for disciplinary action for unprofessional conduct under this chapter.

~~SEC. 36.~~

SEC. 35. Section 4996.13 of the Business and Professions Code is amended to read:

4996.13. Nothing in this article shall prevent qualified members of other professional groups from doing work of a psychosocial nature consistent with the standards and ethics of their respective professions. However, they shall not hold themselves out to the public by any title or description of services incorporating the words psychosocial, or clinical social worker, or that they shall not state or imply that they are licensed to practice clinical social work. These qualified members of other professional groups include, but are not limited to, the following:

(a) A physician and surgeon certified pursuant to Chapter 5 (commencing with Section 2000).

(b) A psychologist licensed pursuant to Chapter 6.6 (commencing with Section 2900).

(c) Members of the State Bar of California.

(d) Marriage and family therapists licensed pursuant to Chapter 13 (commencing with Section 4980).

(e) Licensed professional clinical counselors pursuant to Chapter 16 (commencing with Section 4999.10).

(f) A priest, rabbi, or minister of the gospel of any religious denomination.

~~SEC. 37.~~

SEC. 36. Section 4996.24 of the Business and Professions Code is amended to read:

4996.24. (a) A licensee in private practice who has satisfied the requirements of Section 1870 of Title 16 of the California Code of Regulations may supervise or employ, at any one time, no more than a total of three individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker in that private practice.

(b) A licensed clinical social workers' corporation may employ, at any one time, no more than a total of three individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker for each employee or shareholder who has satisfied the requirements of Section 1870 of Title 16 of the California Code of Regulations.

(c) In no event shall any licensed clinical social workers' corporation employ, at any one time, more than a total of 15 individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. In no event shall any supervisor supervise, at any one time, more than a total of three individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. Persons who supervise individuals registered as either a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker shall be employed full time by the licensed clinical social workers' corporation and shall be actively engaged in performing professional services at and for the licensed clinical social workers' corporation. Employment and supervision within the licensed clinical social workers' corporation shall be subject to all laws and regulations governing experience and supervision gained in a private practice setting.

~~SEC. 38.~~

SEC. 37. Section 4999.12 of the Business and Professions Code is amended to read:

4999.12. For purposes of this chapter, the following terms have the following meanings:

(a) "Board" means the Board of Behavioral Sciences.

(b) "Accredited" means a school, college, or university accredited by the Western Association of Schools and Colleges, or its equivalent regional accrediting association.

(c) "Approved" means a school, college, or university that possessed unconditional approval by the Bureau for Private Postsecondary Education at the time of the applicant's graduation from the school, college, or university.

(d) "Applicant" means an unlicensed person who has completed a master's or doctoral degree program, as specified in Section 4999.32 or 4999.33, as applicable, and whose application for registration as an intern is pending or who has applied for examination eligibility, or an unlicensed person who has completed the requirements for licensure specified in this chapter and is no longer registered with the board as an intern.

(e) "Licensed professional clinical counselor" or "LPCC" means a person licensed under this chapter to practice professional clinical counseling, as defined in Section 4999.20.

(f) "Intern" means an unlicensed person who meets the requirements of Section 4999.42 and is registered with the board.

(g) "Clinical counselor trainee" means an unlicensed person who is currently enrolled in a master's or doctoral degree program, as specified in Section 4999.32 or 4999.33, as applicable, that is designed to qualify him or her for licensure under this chapter, and who has completed no less than 12 semester units or 18 quarter units of coursework in any qualifying degree program.

(h) "Approved supervisor" means an individual who meets the following requirements:

(1) Has documented two years of clinical experience as a licensed professional clinical counselor, licensed marriage and family therapist, licensed clinical psychologist, licensed clinical social worker, or licensed physician and surgeon who is certified in psychiatry by the American Board of Psychiatry and Neurology.

(2) Has received professional training in supervision.

(3) Has not provided therapeutic services to the clinical counselor trainee or intern.

(4) Has a current and valid license that is not under suspension or probation.

(i) "Client centered advocacy" includes, but is not limited to, researching, identifying, and accessing resources, or other activities, related to obtaining or providing services and supports for clients or groups of clients receiving psychotherapy or counseling services.

(j) "Advertising" or "advertise" includes, but is not limited to, the issuance of any card, sign, or device to any person, or the causing, permitting, or allowing of any sign or marking on, or in, any building or structure, or in any newspaper or magazine or in any directory, or any printed matter whatsoever, with or without any limiting qualification. It also includes business solicitations communicated by radio or television broadcasting. Signs within church buildings or notices in church bulletins mailed to a congregation shall not be construed as advertising within the meaning of this chapter.

(k) "Referral" means evaluating and identifying the needs of a client to determine whether it is advisable to refer the client to other specialists, informing the client of that judgment, and communicating that determination as requested or deemed appropriate to referral sources.

(*l*) "Research" means a systematic effort to collect, analyze, and interpret quantitative and qualitative data that describes how social characteristics, behavior, emotion, cognitions, disabilities, mental disorders, and interpersonal transactions among individuals and organizations interact.

(m) "Supervision" includes the following:

(1) Ensuring that the extent, kind, and quality of counseling performed is consistent with the education, training, and experience of the person being supervised.

(2) Reviewing client or patient records, monitoring and evaluating assessment, diagnosis, and treatment decisions of the clinical counselor trainee.

(3) Monitoring and evaluating the ability of the intern or clinical counselor trainee to provide services to the particular clientele at the site or sites where he or she will be practicing.

(4) Ensuring compliance with laws and regulations governing the practice of licensed professional clinical counseling.

(5) That amount of direct observation, or review of audio or videotapes of counseling or therapy, as deemed appropriate by the supervisor.

~~SEC. 39.~~

SEC. 38. Section 4999.90 of the Business and Professions Code is amended to read:

4999.90. The board may refuse to issue any registration or license, or may suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct. Unprofessional conduct includes, but is not limited to, the following:

(a) The conviction of a crime substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. The record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere made to a charge substantially related to the qualifications, functions, or duties of a licensee or registrant under this chapter shall be deemed to be a conviction within the meaning of this section. The board may order any license or registration suspended or revoked, or may decline to issue a license or registration when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or, when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw a plea of guilty and enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(b) Securing a license or registration by fraud, deceit, or misrepresentation on any application for licensure or registration submitted to the board, whether engaged in by an applicant for a license or registration, or by a licensee in support of any application for licensure or registration.

(c) Administering to himself or herself any controlled substance or using any of the dangerous drugs specified in Section 4022, or any alcoholic beverage to the extent, or in a manner, as to be dangerous or injurious to the person applying for a registration or license or holding a registration or license under this chapter, or

to any other person, or to the public, or, to the extent that the use impairs the ability of the person applying for or holding a registration or license to conduct with safety to the public the practice authorized by the registration or license, or the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of the substances referred to in this subdivision, or any combination thereof. The board shall deny an application for a registration or license or revoke the license or registration of any person, other than one who is licensed as a physician and surgeon, who uses or offers to use drugs in the course of performing licensed professional clinical counseling services.

(d) Gross negligence or incompetence in the performance of licensed professional clinical counseling services.

(e) Violating, attempting to violate, or conspiring to violate any of the provisions of this chapter or any regulation adopted by the board.

(f) Misrepresentation as to the type or status of a license or registration held by the person, or otherwise misrepresenting or permitting misrepresentation of his or her education, professional qualifications, or professional affiliations to any person or entity.

(g) Impersonation of another by any licensee, registrant, or applicant for a license or registration, or, in the case of a licensee or registrant, allowing any other person to use his or her license or registration.

(h) Aiding or abetting, or employing, directly or indirectly, any unlicensed or unregistered person to engage in conduct for which a license or registration is required under this chapter.

(i) Intentionally or recklessly causing physical or emotional harm to any client.

(j) The commission of any dishonest, corrupt, or fraudulent act substantially related to the qualifications, functions, or duties of a licensee or registrant.

(k) Engaging in sexual relations with a client, or a former client within two years following termination of therapy, soliciting sexual relations with a client, or committing an act of sexual abuse, or sexual misconduct with a client, or committing an act punishable as a sexually related crime, if that act or solicitation is substantially related to the qualifications, functions, or duties of a licensed professional clinical counselor.

(*l*) Performing, or holding oneself out as being able to perform, or offering to perform, or permitting any clinical counselor trainee or intern under supervision to perform, any professional services beyond the scope of the license authorized by this chapter.

(m) Failure to maintain confidentiality, except as otherwise required or permitted by law, of all information that has been received from a client in confidence during the course of treatment and all information about the client which is obtained from tests or other means.

(n) Prior to the commencement of treatment, failing to disclose to the client or prospective client the fee to be charged for the professional services, or the basis upon which that fee will be computed.

(o) Paying, accepting, or soliciting any consideration, compensation, or remuneration, whether monetary or otherwise, for the referral of professional clients. All consideration, compensation, or remuneration shall be in relation to professional clinical counseling services actually provided by the licensee. Nothing in this subdivision shall prevent collaboration among two or more licensees in a case or cases. However, no fee shall be charged for that collaboration, except when disclosure of the fee has been made in compliance with subdivision (n).

(p) Advertising in a manner that is false, fraudulent, misleading, or deceptive, as defined in Section 651.

(q) Reproduction or description in public, or in any publication subject to general public distribution, of any psychological test or other assessment device, the value of which depends in whole or in part on the naivete of the subject, in ways that might invalidate the test or device.

(r) Any conduct in the supervision of a registered intern, associate clinical social worker, or clinical counselor trainee by any licensee that violates this chapter or any rules or regulations adopted by the board.

(s) Performing or holding oneself out as being able to perform professional services beyond the scope of one’s competence, as established by one’s education, training, or experience. This subdivision shall not be construed to expand the scope of the license authorized by this chapter.

(t) Permitting a clinical counselor trainee or intern under one’s supervision or control to perform, or permitting the clinical

counselor trainee or intern to hold himself or herself out as competent to perform, professional services beyond the clinical counselor trainee's or intern's level of education, training, or experience.

(u) The violation of any statute or regulation of the standards of the profession, and the nature of the services being rendered, governing the gaining and supervision of experience required by this chapter.

(v) Failure to keep records consistent with sound clinical judgment, the standards of the profession, and the nature of the services being rendered.

(w) Failure to comply with the child abuse reporting requirements of Section 11166 of the Penal Code.

(x) Failing to comply with the elder and dependent adult abuse reporting requirements of Section 15630 of the Welfare and Institutions Code.

(y) Repeated acts of negligence.

(z) (1) Engaging in an act described in Section 261, 286, 288a, or 289 of the Penal Code with a minor or an act described in Section 288 or 288.5 of the Penal Code regardless of whether the act occurred prior to or after the time the registration or license was issued by the board. An act described in this subdivision occurring prior to the effective date of this subdivision shall constitute unprofessional conduct and shall subject the licensee to refusal, suspension, or revocation of a license under this section.

(2) The Legislature hereby finds and declares that protection of the public, and in particular minors, from sexual misconduct by a licensee is a compelling governmental interest, and that the ability to suspend or revoke a license for sexual conduct with a minor occurring prior to the effective date of this section is equally important to protecting the public as is the ability to refuse a license for sexual conduct with a minor occurring prior to the effective date of this section.

(aa) Engaging in any conduct that subverts or attempts to subvert any licensing examination or the administration of an examination as described in Section 123.

(ab) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice as a professional clinical counselor, clinical social worker, educational psychologist, or marriage and family therapist.

(ac) Failing to comply with the procedures set forth in Section 2290.5 when delivering health care via telemedicine.

~~SEC. 40.~~

SEC. 39. Section 4999.91 is added to the Business and Professions Code, to read:

4999.91. The board may deny any application, or may suspend or revoke any license or registration issued under this chapter, for any of the following:

(a) Denial of licensure, revocation, suspension, restriction, or any other disciplinary action imposed by this state or another state or territory of the United States, or by any other governmental agency, on a license, certificate, or registration to practice professional clinical counseling or any other healing art shall constitute grounds for disciplinary action for unprofessional conduct. A certified copy of the disciplinary action decision or judgment shall be conclusive evidence of that action.

(b) Revocation, suspension, or restriction by the board of a license, certificate, or registration to practice clinical counseling, clinical social work, professional clinical counseling, marriage and family therapy, or educational psychology shall also constitute grounds for disciplinary action for unprofessional conduct under this chapter.

~~SEC. 41.~~

SEC. 40. Section 4999.455 is added to the Business and Professions Code, to read:

4999.455. (a) A licensed professional in private practice who has satisfied the requirements of subdivision (h) of Section 4999.12 may supervise or employ, at any one time, no more than a total of three individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker in that private practice.

(b) A professional clinical counselor corporation may employ, at any one time, no more than three individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker for each employee or shareholder who has satisfied the requirements of subdivision (h) of Section 4999.12. In no event shall any professional clinical counselor corporation employ, at any one time, more than 15 individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. In no event

shall any supervisor supervise, at any one time, more than three individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker. Persons who supervise individuals registered as a marriage and family therapist intern, clinical counselor intern, or associate clinical social worker shall be employed full time by the professional clinical counselor corporation and shall be actively engaged in performing professional services at and for the professional clinical counselor corporation. Employment and supervision within a professional clinical counselor corporation shall be subject to all laws and regulations governing experience and supervision gained in a private practice setting.

~~SEC. 42.~~

SEC. 41. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, *but would impose limitations on the services provided by a centralized hospital pharmacy*. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets

all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital, in either another physical plant on the same premises or on a separate premises, located within a ~~100 mile~~ *100-mile* radius of the hospital, that is regulated under a hospital's license. *A centralized hospital pharmacy may only provide pharmaceutical services to its own patients who are either admitted or registered patients of a hospital within the same health care system.* Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) Any unit-dose medication produced by a hospital pharmacy under common ownership, as described in Section 4033, shall be barcoded to be readable at the patient's bedside.

(d) A hospital pharmacy may prepare and store a limited quantity of unit-dose medications in advance of receipt of a patient-specific prescription in a quantity as is necessary to ensure continuity of care for an identified population of patients of the hospital based on a documented history of prescriptions for that patient population.

(e) Nothing in this section shall limit the obligation of a hospital pharmacy, hospital, or pharmacist to comply with all applicable federal and state laws.

SEC. 2. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for the purpose of dispensing or administering the drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or

repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third-party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 377 **VERSION: As Amended April 14, 2011**

AUTHOR: Solorio **SPONSOR: California Hospital Association & California Society of Health Systems Pharmacists**

BOARD POSITION: Support if Amended

SUBJECT: Pharmacies: Centralized Hospital Packaging

AFFECTED SECTIONS: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Senate Appropriations Committee hearing scheduled for August 15, 2011.

EXISTING LAW:

1. Defines a hospital pharmacy as a pharmacy licensed by the board that is located inside a hospital as specified.
2. Allows a hospital pharmacy to be located outside of the hospital building if the hospital pharmacy is on the California Department of Public Health's consolidated license and if the pharmacy is only providing pharmacy services to inpatients of the hospital.
3. Defines "manufacturer" and exempts compounding, as specified from the definition.

THIS BILL WOULD:

1. Specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius, which is regulated under a hospital's license.
2. Specify that these services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.
3. Specify that unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership must be bar-coded to be readable at the patient's bedside.
4. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
5. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for purposes of administering medication pursuant to a prescription order.
6. Require a pharmacy performing such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:
According to the author, "technology is now capable of providing hospitals with a method to deliver barcoded unit-doses to in-patients' bedsides. However, the cost of this technology renders it virtually impossible for hospitals to do within the structures of the current hospital pharmacy. In addition, because the new central pharmacy would serve multiple hospitals (though the hospitals are under common ownership), currently lawful hospital pharmacy activities might run afoul of the manufacturing law." The author notes that the potential to finally and effectively address in-patient medication errors is greatly expanded by this proposal.

FISCAL IMPACT:
Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:
Amendments to this measure clarify that the centralized pharmacy services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.

This proposal appears consistent with the board's mission statement, "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." This proposal would allow a hospital to leverage existing technology to prepare unit-dose medications that include bar-coding technology that must be readable at the patient's bedside.

Over the years the board has evaluated the issue of medication errors and reviewed materials and heard presentations from experts on what can be done to reduce such errors. Bar-coding technology has been identified as one tool that can be used to reduce medication errors. In 2004, the FDA established bar code label requirements for human drug and biological products (21 CFR Parts 201, 606, et al.) The FDA included in its guidance document, "Bar codes will allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This new system is intended to help reduce the number of medication errors that occur in hospitals and health care settings." (Hospitals are exempt from the FDA requirement to barcode unit-dose packages.) In 2004, the FDA also noted that hospitals that were using bar-coding at that time avoided 50% of the adverse drug events caused by errors in the distribution and administration of prescriptions.

A summary from a study published in 2006, "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy, Poon et. Al," included:

> "…our study results suggest that bar code technology in a hospital pharmacy may substantially reduce serious dispensing errors. In particular, it may target several types of dispensing errors that may frequently harm patients, including wrong medication, wrong dose, or wrong formulation errors. However, the scanning technology should be

configured to ensure that all doses are scanned at least once during the dispensing process. If optimally configured, this technology may be an important addition to the medication safety armamentarium."

Further, a portion of the discussion from this study also included:

"The rates of target dispensing errors and potential ADEs substantially decreased after the implementation of bar code technology: The target dispensing error rate decreased by 85%, and the rate of all dispensing-related potential ADEs decreased by more than 60%."

As this measure does not currently specify the requirements of the bar-coding, the board may want to consider offering an amendment to clarify what information should be contained within bar-code. The board may want to consider the FDA requirement elements established in 21 CFR Parts 201, 606, et al.

PRIOR BOARD DISCUSSION and ACTION:

During the May Board Meeting, the board spoke in support of this measure. Technical issues were raised by counsel during this discussion about some clarity issues. As a result, the board voted to establish a Support if Amended position. Following the meeting, board staff conveyed the board's position to CSHP and discussed the changes being sought. Subsequent discussions with CSHP revealed that the board's request for amendments may present some challenges to the bill moving forward. However, CSHP has confirmed their commitment to working with the board to clarify these items, but has informally requested that this could perhaps be accomplished as clean-up legislation next year if these changes cannot be accommodated this year.

Board staff was recently advised that this will be a two-year bill.

PREVIOUS LEGISLATION:

The board previously supported AB 1370 (Solorio, 2009) which contained provisions similar to this bill.

The board previously supported AB 2077 (Solorio, 2010) which contained provisions similar to this bill. This bill was vetoed by the governor.

"This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California."

SUPPORT/OPPOSITION:

<u>Support:</u>

California Hospital Association (sponsor)
California Pharmacists Association
Antelope Valley Hospital

California Society of Health-System Pharmacists
Mercy General Hospital
Sharp
St. Joseph's Medical Center, Pharmacy Department
Touro University, College of Pharmacy
Individual Pharmacists

Opposition:
None of file

HISTORY:

Date	**Action**
July 5	In committee: Set, second hearing. Hearing canceled at the request of author.
June 21	In committee: Set, first hearing. Hearing canceled at the request of author.
June 14	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (June 13). Re-referred to Com. on APPR.
May 26	Referred to Com. on B., P. & E.D.
May 12	In Senate. Read first time. To Com. on RLS. for assignment.
May 12	Read third time. Passed. Ordered to the Senate. (Ayes 70. Noes 0. Page 1356.)
May 9	Read second time. Ordered to consent calendar.
May 5	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 4).
Apr. 26	From committee: Do pass and re-refer to Com. on APPR. With recommendation: to consent calendar. (Ayes 9. Noes 0.) (April 26). Re-referred to Com. on APPR.
Apr. 25	Re-referred to Com. on B., P. & C.P.
Apr. 14	From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Apr. 12	From committee: Do pass and re-refer to Com. on B., P. & C.P. (Ayes 19. Noes 0.) (April 12). Re-referred to Com. on B., P. & C.P.
Mar. 7	Referred to Coms. on HEALTH and B., P. & C.P.
Feb. 15	From printer. May be heard in committee March 17.
Feb. 14	Read first time. To print.

AMENDED IN SENATE JULY 1, 2011

AMENDED IN SENATE JUNE 20, 2011

AMENDED IN ASSEMBLY APRIL 27, 2011

AMENDED IN ASSEMBLY APRIL 13, 2011

AMENDED IN ASSEMBLY MARCH 21, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 507

Introduced by Assembly Member Hayashi

February 15, 2011

An act to amend Sections 124960 and 124961 of, and to repeal Section 11453 of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 507, as amended, Hayashi. Pain management.

(1) Existing law authorizes the Department of Justice to employ a physician to interview and examine any patient in connection with the prescription, possession, or use of a controlled substance, requires the patient to submit to the interview and examination, and authorizes the physician to testify in prescribed administrative proceedings.

This bill would repeal that provision.

(2) Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California~~, and the~~. *The* violation of specified provisions of the act is a crime. Existing law authorizes a physician and surgeon to prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition, drugs or prescription controlled substances for the

treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

This bill would conform findings and declarations and other references to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 11453 of the Health and Safety Code is repealed.

SEC. 2. Section 124960 of the Health and Safety Code is amended to read:

124960. The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from pain or a condition causing pain, including, but not limited to, intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from pain or a condition causing pain, including, but not limited to, intractable pain may require referral to a physician with expertise in the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. In some cases, pain or a condition causing pain, including, but not limited to, intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for pain or a condition causing pain, including, but not limited to, intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in pain or a condition causing pain, including, but not limited to, intractable

pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from pain or a condition causing pain, including, but not limited to, intractable pain has the option to request or reject the use of any or all modalities to relieve his or her pain.

(i) A physician treating a patient who suffers from pain or a condition causing pain, including, but not limited to, intractable pain may prescribe a dosage deemed medically necessary to relieve pain as long as the prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from pain or a condition causing pain, including, but not limited to, intractable pain, has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for pain or a condition causing pain, including, but not limited to, intractable pain. However, that physician shall ~~refer the patient to~~ *inform the patient that there are* physicians who treat pain or a condition causing pain, including, but not limited to, intractable pain with methods that include the use of opiates.

SEC. 3. Section 124961 of the Health and Safety Code is amended to read:

124961. Nothing in this section shall be construed to alter any of the provisions set forth in Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from pain or a condition causing pain, including, but not limited to, intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.

(b) A patient who suffers from pain or a condition causing pain, including, but not limited to, intractable pain has the option to choose opiate medications to relieve that pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or

device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for pain or a condition causing pain, including, but not limited to, intractable pain. However, that physician shall inform the patient that there are physicians who treat pain and whose methods include the use of opiates.

(d) A physician who uses opiate therapy to relieve pain or a condition causing pain, including, but not limited to, intractable pain may prescribe a dosage deemed medically necessary to relieve the patient's pain, as long as that prescribing is in conformance with Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 507 **VERSION: As Amended July 1, 2011**

AUTHOR: Hayashi **SPONSOR: American Cancer Society**

BOARD POSITION: Oppose (April 27, 2011 version)

SUBJECT: Pain Management

Affected Sections: Amend Sections 124960 and 124961 of the Health and Safety Code and repeal Section 11453 of the Health and Safety Code.

CURRENT STATUS: Senate Appropriations Committee hearing scheduled for August 15, 2011.

EXISTING LAW:

1. Business and Professions Code section 4301 authorizes the board to take action against any holder of a license that is guilty of unprofessional conduct as specified. Unprofessional conduct includes several elements including the clearly excessive furnishing of controlled substances in violation of Health and Safety Code section 11153(a).
2. Health and Safety Code section 11453 authorizes the Department of Justice to employ a physician to interview and examine any patient for whom any Scheduled I – III controlled substance has been furnished as specified.
3. Health and Safety Code section 124960 sets forth legislative findings and declarations including the state's right and duty to control the illegal use of opiates, inadequate treatment of acute and chronic pain is a significant health program, patients that suffer from severe chronic intractable pain should have access to proper treatment of his or her pain, many patients suffering require referral to a physician with expertise, opiates can be an accepted treatment for patients in severe chronic intractable pain and provides that a patient's physician may refuse to prescribe opiate medication however the physician shall inform that patient about physicians that specialize in such treatment.
4. Establishes the Pain Patient's Bill of Rights that includes:
    a. A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her pain.

b. A patient has the option to choose opiate medications to relieve the pain as specified.
c. A physician's right to refuse to prescribe opiate medication, however requires the physician to inform the patient about physicians that specialize in such treatment.
d. A physician who uses opiate therapy may prescribe dosage deemed medically necessary consistent with Section 2241.5 of the Business and Professions Code.
e. A patient may request that the physician provide an identifying notice of the prescription for purposes of emergency treatment or law information.
f. Nothing in the section limits any reporting or disciplinary provisions against those who violate prescribing practices or applicability of federal and state laws that regulate dangerous drugs or controlled substances.

AS AMENDED THIS BILL WOULD:

1. Repeals the provisions authorizing the DOJ to employ a physician to interview and examine any patient for whom any Scheduled I – III controlled substance has been furnished as specified.
2. Replaces the clause "severe chronic intractable pain" with "pain or a condition causing pain, including, but not limited to, intractable pain."

AUTHOR'S INTENT:

According to the author's office, this bill eliminates ambiguities and inconsistencies in the Intractable Pain Treatment Act that negatively affect appropriate clinical interpretation.

COMMENTS:

As originally introduced this bill could have limited the board's ability to discipline a pharmacist's license when they fail to exercise their professional judgment.

In the past three calendar years, the board has initiated 36 investigations alleging violations of Health and Safety Code section 11153. This code establishes the corresponding responsibility that rests with a pharmacist who fills a prescription for a controlled substance and the board relies upon B&PC 4301(d) to establish such action as unprofessional conduct for purposes of discipline.

The bill in its current form removes the condition that the furnishing of the controlled substances must be clearly excessive to constitute unprofessional conduct and would instead provide that unprofessional conduct includes any furnishing of controlled

substances in violation of those prescribed provisions relating to the prescription of controlled substances by a practitioner.

PREVIOUS BOARD DISCUSSION and ACTION

During the board meeting, members discussed the measure and the challenges that were presented with the amendments to the board's unprofessional conduct provisions. After discussion, the board voted to establish an "oppose" position on the measure because the proposed amendments compromised the board's consumer protection mandate and conflicted with existing case law. Board staff conveyed the board's position both verbally and in writing. The board's Executive Officer and Board President also met with Assembly Member Hayashi as well as staff and representatives of the sponsor of this measure. As a result, the provisions amending the board's unprofessional conduct statute were removed.

FISCAL IMPACT:

In its current form board staff does not anticipate any significant impact to the board. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Support

American Cancer Society (Sponsor)
American Chronic Pain Association
American Society for Pain Management Nursing
California Academy of Physician Assistants
Feinberg Medical Group
For Grace
Hollywood Presbyterian Medical Center
Medical Board of California
Southern California Cancer Pain Initiative
USC/Keck School of Medicine CARE Team/Palliative Medicine Department

Opposition

None on file

HISTORY:

Date	Action
July 1	Read second time and amended. Re-referred to Com. on APPR.
June 30	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 8. Noes 1.) (June 27).
June 20	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
June 2	Referred to Com. on B., P. & E.D.
May 19	In Senate. Read first time. To Com. on RLS. for assignment.
May 19	Read third time. Passed. Ordered to the Senate. (Ayes 55. Noes 20. Page 1470.)
May 16	Read second time. Ordered to third reading.
May 12	From committee: Do pass. (Ayes 13. Noes 3.) (May 11).
May 4	From committee: Do pass and re-refer to Com. on APPR. (Ayes 6. Noes 0.) (May 3). Re-referred to Com. on APPR.

Apr. 28 Re-referred to Com. on B., P. & C.P.
Apr. 27 From committee: Do pass and re-refer to Com. on B., P. & C.P. (Ayes 13. Noes 4.) (April 26). Re-referred to Com. on B., P. & C.P. From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Apr. 14 Re-referred to Com. on HEALTH.
Apr. 13 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 5 In committee: Hearing postponed by committee.
Mar. 22 Re-referred to Com. on HEALTH.
Mar. 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 3 Referred to Coms. on HEALTH and B., P. & C.P.
Feb. 16 From printer. May be heard in committee March 18.
Feb. 15 Read first time. To print.

AMENDED IN ASSEMBLY MAY 26, 2011

AMENDED IN ASSEMBLY MAY 11, 2011

AMENDED IN ASSEMBLY MARCH 25, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 1280

Introduced by Assembly Member Hill
(Coauthor: Assembly Member Hagman)

February 18, 2011

An act to amend, repeal, and add Section 11100 of, and to add and repeal Section 11100.02 of, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1280, as amended, Hill. Ephedrine: retail sale.

(1) Existing law classifies controlled substances into 5 schedules, with the most restrictive limitations placed on controlled substances classified in Schedule I, and the least restrictive limitations placed on controlled substances classified in Schedule V. A controlled substance in any of the schedules may be possessed or dispensed only upon a lawful prescription, as specified. Existing law does not classify ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within any of these 5 schedules, but provides that it is a crime, punishable as specified, for a person in this state who engages in specified transactions involving those drugs to fail to submit a report to the Department of Justice of all of those transactions, or to fail to submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified. Existing law prohibits the sale of more than 3 packages or 9 grams of a

nonprescription product containing ephedrine or the other drugs, as specified.

This bill would instead provide that it is a misdemeanor, punishable as specified, for any retail distributor, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority, to sell or distribute to a person specified amounts of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine within specified time limits, to sell or distribute any of those substances to a person whose information has generated an alert, or, except under specified conditions, to sell or distribute to any purchaser a nonprescription product containing any amount of those substances. The bill would contain provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, as specified.

The bill would require retail distributors to transmit, *on and after July 1, 2012,* sale information to the National Precursor Log Exchange (NPLEx) for purposes of determining whether the sale would violate these provisions. The bill would require the Department of Justice to enter into a memorandum of understanding with the National Association of Drug Diversion Investigators regarding the transaction records in NPLEx, as specified. The bill would provide that the information in the system may not be used for any purpose other than to meet the requirements of, or comply with, this act or a certain federal act, as specified. The bill would specify legislative findings and intent. The bill's provisions would remain in effect only until January 1, 2018. By creating a new crime, this bill would impose a state-mandated local program.

(2) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11100 of the Health and Safety Code is amended to read:

11100. (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.
(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro;

dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).

(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).

(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the Department of Justice; driver's license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient

of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) Any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subsection (d) of Section 814 of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 2. Section 11100 is added to the Health and Safety Code, to read:

11100. (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.
(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.

(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.
(37) Iodine or tincture of iodine.
(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).
(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.
(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (i) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (ii) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person

or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the State Department of Public Health; registration number issued by the federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the Department of Justice; driver's license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and

the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any manufacturer or wholesaler licensed by the California State Board of Pharmacy that sells, transfers, or otherwise furnishes a substance to a licensed pharmacy, physician, dentist, podiatrist, or veterinarian, or a retail distributor as defined in subdivision (h), provided that the manufacturer or wholesaler submits records of any suspicious sales or transfers as determined by the Department of Justice.

(4) Any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

(5) A state-licensed health care facility that administers or furnishes a substance to its patients.

(6) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine,

pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subsection (d) of Section 814 of Title 21 of the United States Code as an exempt product.

(7) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(8) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for any retail distributor to (A) sell in a single transaction more than three

packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (B) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit

does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(j) This section shall become operative on January 1, 2018.

SEC. 3. Section 11100.02 is added to the Health and Safety Code, to read:

11100.02. (a) Notwithstanding any other law, it is unlawful for any retail distributor to knowingly do the following, except pursuant to a valid prescription from a licensed practitioner with prescriptive authority:

(1) To sell or distribute to the same purchaser within any 30-day period more than nine grams, or within any day more than 3.6 grams, of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the

federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.) by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(2) To sell or distribute any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to a person whose information has generated an alert as described in paragraph (3) of subdivision (d) regarding that sale.

(3) To sell or distribute to any purchaser a nonprescription product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, except under the following conditions:

(A) The purchaser shall produce valid government-issued photo identification.

(B) The purchaser shall sign a written or electronic log showing the following:

(i) The date and time of the transaction.

(ii) The identification number presented.

(iii) The agency issuing the identification and the type of identification issued.

(iv) The name, date of birth, and address of the purchaser.

(v) The amount of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in the material, compound, mixture, or preparation sold.

(b) The retail distributor shall store any product containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine either behind the counter or in a locked cabinet so that the customer does not have access to the product.

(c) (1) To facilitate the monitoring of the sales of nonprescription products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, the retail distributor shall record all of the following information at the point of sale regarding the proposed transaction for the purpose of complying with this section or the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act, and for no other purpose:

(A) The date and time of the transaction.

(B) The identification number of the purchaser, issuing agency of the identification, and the type of identification used.

(C) The name, date of birth, and address of the purchaser verified through a photo identification of the purchaser.

(D) The name, quantity of packages, and total gram weight of ephedrine base, pseudoephedrine base, norpseudoephedrine base, or phenylpropanolamine base contained in a product or products purchased, received, or otherwise acquired.

(E) The name or initials of the person making the sale.

(2) ~~Beginning January 1, 2013~~ *On and after July 1, 2012*, the retail distributor shall transmit the information immediately to the National Precursor Log Exchange (NPLEx) administered by the National Association of Drug Diversion Investigators (NADDI) for purposes of determining whether the proposed sale would violate this section and therefore may not proceed, provided that the NPLEx system is available to retailers in the state without a charge for accessing the system. The transaction information shall not be accessed, stored, or used by the retail distributor for any purpose other than to meet the requirements set forth in this section or to comply with the provisions of the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. The retail distributor shall not maintain a separate copy of the transaction information except as required by the federal Combat Methamphetamine Epidemic Act of 2005.

(3) (A) A retail distributor shall provide notice electronically, in writing, or by signage to purchasers that the information collected pursuant to the federal Combat Methamphetamine Epidemic Act of 2005 and this section shall be provided to law enforcement for purposes of determining the legality of a proposed sale.

(B) The Legislature finds that it is necessary for probable cause to be demonstrated to trigger an investigation in connection with an individual whose requested purchase is denied by the system a single time.

(4) This subdivision shall not be construed to require a retail distributor to maintain state-required records relating to the sale of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in a separate location or log from records required by federal law to be kept with respect to those products.

(5) The recording requirements specified in this subdivision shall not apply to the sale of a single package containing not more

than 60 milligrams of pseudoephedrine, consistent with the federal Combat Methamphetamine Epidemic Act of 2005.

(6) If a retail distributor experiences mechanical or electronic failure of the system and is unable to comply with the recording requirements of this subdivision, the retail distributor shall maintain the required records in a written log or an alternative electronic recordkeeping mechanism until the retail distributor is able to comply with the recording requirements of this subdivision.

(d) (1) Provided that the department executes a memorandum of understanding (MOU) with NADDI governing access, pursuant to this subdivision, NADDI shall forward California transaction records in NPLEx to the Department of Justice weekly and provide real-time access to NPLEx information through the NPLEx online portal to law enforcement in the state as authorized by the department.

(2) The system shall allow retail distributors of products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine to enter into the database the information specified in subdivision ~~(d)~~ *(c)* regarding the proposed sale of those products.

(3) The system shall be capable of providing the retail distributor with an immediate real-time alert any time any provision of this section is being violated by a proposed sale.

(4) The MOU shall state that no party to the MOU nor any entity under contract to provide the electronic authorization and monitoring system shall be authorized to use the information contained in the system for any purpose other than those set forth in this section, the federal Combat Methamphetamine Epidemic Act of 2005, or any regulation adopted pursuant to this section or that act. However, the system operator shall be authorized to analyze the information for the sole purpose of assessing and improving the performance and efficacy of the system. In addition, the MOU shall require that any retail distributor's access to the electronic authorization and monitoring system's database is limited solely to records of sales transactions made by that retail distributor, which access shall be solely for purposes of complying with the federal Combat Methamphetamine Epidemic Act of 2005 or this section, or to respond to a duly authorized law enforcement request or court order for information collected under that act or this section.

(5) The system's security program shall comply with the security standards for the Criminal Justice Information System of the Federal Bureau of Investigation and may be audited once a year by the department.

(6) A retail distributor's use of the system shall be subject to Section ~~56.10~~ *56.101* of the Civil Code. A retail distributor shall not maintain any records collected under this system for longer than two years, or as otherwise required by the federal Combat Methamphetamine Epidemic Act of 2005.

(7) Law enforcement access to the system shall be recorded by means of a unique access code for each individual accessing the system. Each user's history shall be maintained and may be audited by the department.

(8) The department may submit recommendations to NADDI regarding system changes to assist in identifying false identification cards.

(e) The State Board of Equalization shall notify all retailers about the requirement to submit transactions to NPLEx no later than ~~September~~ *April* 1, 2012.

(f) This section shall not apply to a health care practitioner with prescriptive authority who is currently licensed in this state.

(g) (1) A first violation of this section is a misdemeanor.

(2) Any person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this section, the following terms have the following meanings:

(1) "Department" means the Department of Justice.

(2) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in amounts at or below that specified in subdivision (a). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(j) This section shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1280 **VERSION: As Amended May 26, 2011**

AUTHOR: Hill **SPONSOR: Author**

BOARD POSITION: Watch

SUBJECT: Ephedrine: Retail Sale

AFFECTED SECTIONS: An act to amend, repeal, and add Section 11100 of, and to add and repeal Section 11100.02 of, the Health and Safety Code

CURRENT STATUS: Assembly Public Safety Hearing scheduled for May 3, 2011.

EXISTING LAW:
Health and Safety Code section 11100:

1. Requires any manufacturer, wholesaler, retailer or other person or entity in this state that sells, transfers or otherwise furnishes specified substances, to report to the Department of Justice (DOJ). These substances are controlled substances and/or chemical precursors for manufacture of illicit drugs.
2. Specifies that such entities, prior to selling, transferring or otherwise furnishing any specified substance shall require a letter of authorization that includes the current valid business license or DEA registration, and the address of the business and proper identification of the purchaser. Information collected must also include how the substance is to be used, and specifies that this information shall be maintained for three years.
3. Defines proper identification to include two of the following:
    a. Federal tax identification number
    b. Seller's permit identification number
    c. City or county business license number
    d. State Department of Public Health License
    e. Registration issued by federal Drug Enforcement Administration
    f. Precursor business permit number issued by the Bureau of Narcotic Enforcement
    g. Driver's license
    h. Other identification issued by a state.
4. Requires any entity that exports a substance, as provided in this section, to any person or business located in a foreign country to notify the DOJ of the transaction and specifies that the notification shall include the name and quantity of the substance, the name, address and business identification number (if assigned by the foreign country).
5. Specifies that the DOJ may require such reports on a monthly basis.
6. Requires reporting not less than 21 days in advance of a transaction to any entity in the US or on a monthly basis as determined by the DOJ.
7. Requires the seller to affix his or her signature or provide other identification to the purchaser and specifies requirement for the use of a common carrier.

8. Specifies exemptions to these provisions for the following:
    a. Pharmacist or other authorized person who sells or furnishes a substance pursuant to a prescription.
    b. Any physician, dentist, podiatrist or veterinarian who administers or furnishes a substance to his or her patients.
    c. Manufacturers and board licensed wholesalers from these provisions as specified, but requires records of suspicious sales and transfers as determined by the DOJ.
    d. Any analytical research facility that is registered with the federal DEA.
    e. A state-licensed health care facility that administers or furnishes a substance to its patients.
    f. Specified products that are sold over the counter without a prescription, unless the individual transaction involves more than three packages or nine grams of the substance.
    g. Any transfer or a substance for lawful disposal as waste.
9. Creates penalties for non-compliance, including jail time and fines as specified.
10. Specifies the conditions under which it is unlawful to sell, transfer or otherwise furnish a substance to a person under 18 years of age.
11. Provides that it is unlawful for a retailer to sell more than three packages of ephedrine containing products in a single transaction or sell more than nine grams of ephedrine containing products as specified.
12. Defines several terms for purposes of this article.
13. Specifies that these provisions preempt all local ordinances or regulations governing the sale of specified products.

THIS BILL WOULD:

Until January 1, 2018 amend Section 11100 of the Health and Safety Code to move some provisions into Section 11100.02.

Until January 1, 2018 add Section 11100.02 of the Health and Safety Code:

1. Specify it is unlawful for a retailers to:
    a. Sell to the same purchaser within 30-days, more than nine grams or within any day more than 3.6 grams of ephedrine containing products
    b. Sell ephedrine containing products to a person whose information has generated an alert, as specified
    c. Sell ephedrine containing products without collecting proper identification as specified
2. Require a retail distributor to store ephedrine containing products behind the counter or in a locked cabinet.
3. Establish recordkeeping elements including:
    a. Date and time of transaction
    b. Purchaser identification information - name, date of birth and address
    c. Name, quantity of packages and total gram weight of ephedrine containing products
    d. Initial of person making the sale
4. Beginning on or after July 1, 2010, require the retailer to immediately transmit the information required above to the National Precursor Log Exchange (NPLEx) to determine if the proposed sale would violate the transaction limits for ephedrine containing products. Further it would:

a. Prohibit the retailer from using this information for any other purpose
b. Require the retailer to post a notice regarding the collection of this information
c. Specify that a separate record of this information shall not also be required to maintain state-required records in a separate location
d. Exempt from this requirement the sale of a single package containing not more that 60 milligrams of an ephedrine product
e. Establish system requirements and implementation options.

5. Require the State Board of Equalization to notify retailers of this requirement
6. Exempt CA licensed health care practitioners with prescriptive authority.
7. Define various terms for purposes of this section.

Effective January 1, 2018

1. Restore Section 11100 to its current form.
2. Repeal Section 11100.02.

FISCAL IMPACT:
Enforcement of these provisions would reside primarily with the Department of Justice. The board does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS:
The federal government passed The Combat Methamphetamine Act of 2005 to establish restrictions on the sale of over-the-counter (nonprescription) products containing ephedrine (EPH), pseudoephedrine (PSE), or phenylpropanolamine (PPA) - classified under the federal Controlled Substances Act as "scheduled listed chemical products." The act changed the limit amount of product that could be sold by a retailer to an individual and the amount that can be purchased by an individual. The requirements of this Act include blister packaging for nonliquid dosages, buyer's proof of identification, recordkeeping by the seller, and penalties for violators of the new restrictions.

Arguments in support of this measure indicate that the proposed solution leverages and existing database (NPLEx) that is used by 13 other states is funded by manufacturers. Arguments in opposition to this proposed solution include privacy concerns about patient information and who would have access to the information as well as if a California specific database, similar to CURES would be a viable option.

PRIOR BOARD DICUSSION and ACTION:
During the May Board Meeting, the board discussed the provisions of this measure and established a "Watch" position on the measure. Since that time the bill has been amended twice, updating a reference to the Civil Code and to change in effective date for the reporting requirement from "January 1, 2013" to "on or after July 1, 2012."

PREVIOUS/RELATED LEGISLATION:

Previous

AB 1455 (Hill, 2009) contained similar provisions but stalled in policy committee. The board did not have a position on this measure.

Related

SB 315 (Wright, 2011) contains provisions that are also intended to reduce the sales of ephedrine products, however it takes a much different approach. Generally, SB 315 would prohibit the sale of ephedrine product to an individual except pursuant to a prescription. SB 315 is a two-year bill.

SUPPORT/OPPOSITION:

Support

Alameda County Sheriff's Office
Alliance for Patient Access, California Chapter
Alameda Health Consortium
Bayer Health Care
BIOCOM
Calaveras County Sheriffs' Department
California Alliance for Retired Americans
California Black Health Network
California Chamber of Commerce
California District Attorneys Association
California Healthcare Institute
California Hispanic Chamber of Commerce
California Manufacturers and Technology Association
California Medical Association
California Pharmacists Association
California Primary Care Association
California Retailers Association
California State Sheriffs' Association
Community Clinic Association of LA County
Consumer Healthcare Products Association
Johnson and Johnson
Healthy African American Families II
Kern County Sheriff
Lassen County Sheriff's Office
Los Angeles County Medical Association
Los Angeles Society of Allergy, Asthma & Clinical Immunology, Inc.
Marin Medical Society
Napa County Medical Society
National Association of Chain Drug Stores
National Federation of Independent Business
Orange County Business Council
Orange County Sheriff-Coroner Department
Peace Officers Research Association of California
Pfizer, Inc.
Reckitt Benckiser
Rite Aid
Sacramento County Sheriff's Department
San Francisco Chamber of Commerce
San Joaquin County Sheriff
Sanofi-Aventis
Santa Clara County Medical Association
Santa Cruz County Sheriff-Coroner
Shasta County Sheriff
Siskiyou County Sheriff's Department
Solano County Medical Society
Sonoma County Medical Association
Valley Industry & Commerce Association (VICA)
Walgreens
Yolo County Sheriff's Department

Opposition

American Civil Liberties Union
California Department of Justice
California Narcotics Officers' Association
California Public Defenders Association
Electronic Frontier Foundation
Los Angeles County District Attorney
National Narcotics Officers Association Coalition
Privacy Rights Clearinghouse

HISTORY:

Date	Action
July 6	From committee: Do pass and re-refer to Com. on APPR. (Ayes 4. Noes 1.) (July 5). Re-referred to Com. on APPR.
June 21	From committee: Do pass and re-refer to Com. on JUD. (Ayes 6. Noes 0.) (June 21). Re-referred to Com. on JUD.
June 8	Referred to Coms. on PUB. S. and JUD.
May 31	In Senate. Read first time. To Com. on RLS. for assignment.
May 31	Read third time. Passed. Ordered to the Senate. (Ayes 79. Noes 0. Page 1636.)
May 26	Read third time and amended. Ordered to third reading. (Page 1558.)
May 19	Read second time. Ordered to third reading.
May 18	From committee: Do pass. (Ayes 16. Noes 0.) (May 18).
May 12	Re-referred to Com. on APPR.
May 11	Read second time and amended.
May 10	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (May 3).
Mar. 29	Re-referred to Com. on PUB. S.
Mar. 25	Referred to Com. on PUB. S. From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
Feb. 20	From printer. May be heard in committee March 22.
Feb. 18	Read first time. To print.

AMENDED IN ASSEMBLY JULY 7, 2011

AMENDED IN SENATE MAY 10, 2011

AMENDED IN SENATE APRIL 14, 2011

AMENDED IN SENATE MARCH 22, 2011

SENATE BILL No. 360

Introduced by Senator DeSaulnier

February 15, 2011

An act to amend Sections 11161.5, 11162.1, 11165, *and* 11165.1, ~~and 11212~~ of, and to add Sections 11165.2 and 11165.3 to, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 360, as amended, DeSaulnier. Controlled Substance Utilization Review and Evaluation System.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice, contingent upon the availability of adequate funds from various funds related to health care, as specified, to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law defines a security printer as a person approved to produce controlled substance prescription forms. Existing law requires that prescription forms for controlled substance prescriptions be obtained from security printers approved by the Department of Justice. These provisions authorize the department to approve a security printer who provides specified information to the department, including the location,

names, and titles of the applicant's agent for service of process, all principal corporate officers, if any, and all managing general partners, if any. Existing law also requires those persons to provide a signed statement indicating whether they have ever been convicted of, or pled no contest to, a violation of any law or ordinance. Existing law authorizes the department to revoke its approval of a security printer for a violation of these provisions or action that would permit a denial.

This bill would expand those requirements imposed on an applicant for approval as a security printer to additionally require the applicant to provide the location, names, and titles of any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms and require those persons to submit the signed statement described above. The bill would also make conforming and related changes. In addition, the bill would require that controlled substance prescription forms provided in person be restricted to established customers. The bill would require security printers to obtain photo identification from the customer and maintain a log of the information, and to report any theft or loss of controlled substance prescription forms to the department via fax or e-mail within 24 hours of the incident. The bill would also require that controlled substance prescription forms be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California. The bill would specify penalties for certain violations, including, among others, failure to comply with security printer guidelines, failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms, and theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms. By creating new crimes, this bill would impose a state-mandated local program.

Existing law governs the prescription forms for controlled substances. Among other things, the forms are required to include the preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

This bill would also require the forms to include the address of the prescribing practitioner. The bill would make an additional change relating to forms ordered for use by prescribers when treating patients in licensed health care facilities or certain clinics that are exempt from other requirements governing these forms. The bill would provide that

prescription forms that are not in compliance with these provisions shall not be accepted after July 1, 2012.

The bill would establish a specified process by which a licensed health care practitioner or a pharmacist may obtain approval to access information stored on the Internet regarding the controlled substance history of a patient, as specified.

The bill would require that the theft or loss of prescription forms be reported immediately to the department, as specified. The bill would also require the department to conduct audits of the CURES prescription drug monitoring system and authorize the department to establish a system for issuing citations, and for assessing and imposing administrative fines, not to exceed $2,500 for each violation, that would be deposited in the CURES Program Special Fund, for violations of the program, as specified.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual

owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (*l*) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant

to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit

and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or e-mail within 24 hours of the theft or loss.

(*l*) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or

action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(m) The following violations by security printers shall be punishable pursuant to subdivision (n):

(1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.

(2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.

(3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

(1) For a first violation, a fine not to exceed one thousand dollars ($1,000).

(2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars ($2,500) for each violation.

(3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.

SEC. 2. Section 11162.1 of the Health and Safety Code is amended to read:

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in

subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.

SEC. 3. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

SEC. 4. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the Department of Justice, and the department may release to that practitioner or pharmacist, the electronic history of controlled substances dispensed to an individual under his or her care based on data

contained in the CURES Prescription Drug Monitoring Program (PDMP).

(A) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within 10 days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical

Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

SEC. 5. Section 11165.2 is added to the Health and Safety Code, to read:

11165.2. (a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.

(b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.

(c) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars ($2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.

(4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter

5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.

(6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:

(A) A citation may be issued without the assessment of an administrative fine.

(B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide

support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.

(f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.

(g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

SEC. 6. Section 11165.3 is added to the Health and Safety Code, to read:

11165.3. The theft or loss of prescription forms shall be reported immediately *by the security printer or affected prescriber* to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. This notification may be done in writing utilizing the Bureau of Narcotic Enforcement 1175 Reporting Theft/Loss Form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

~~SEC. 7. Section 11212 of the Health and Safety Code is amended to read:~~

~~11212. (a) Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes those substances classified in paragraphs (81) and (82) of subdivision (b) of Section 11054 of the Health and Safety Code, upon registration with and approval by the Department of Justice for use of those substances in bona fide research, instruction, or analysis.~~

~~(b) That research, instruction, or analysis shall be carried on only under the auspices of the individual identified by the registrant as responsible for the research. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.~~

~~(c) The Department of Justice may withdraw approval of the use of such substances at any time. The department may obtain~~

~~and inspect at any time the records required to be maintained by this section.~~

~~SEC. 8.~~

SEC. 7. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 360 **VERSION: As Amended July 7, 2011**

AUTHOR: DeSaulnier **SPONSOR: Attorney General**

BOARD POSITION: Watch

SUBJECT: Controlled Substance Utilization Review and Evaluation System (CURES)

Affected Sections: Amend Sections 11161.5, 11162.1, 11165, 11165.1, and add 11165.2 and 11165.3 to the Health and Safety Code

CURRENT STATUS: Assembly Appropriations Committee hearing scheduled for August 17, 2011

EXISTING LAW:
The Uniform Controlled Substances Act places controlled substances into four schedules, found in Health and Safety Code sections 11054 through 11057.

Health and Safety Code sections 11161.5 – 11162.1 establish guidelines for the printing of controlled substance security prescription forms, which is managed by the California Department of Justice (DOJ) California Security Prescription Printer Program. These provisions provide for the approval (or denial) of applicants who wish to be approved printers of security controlled substances prescription forms and requires approved printers to verify prescribers with the appropriate licensing board prior to printing; delivery of controlled substance prescription forms; and maintenance of records. These provisions also specify the content required to be printed on a security prescription form.

Health and Safety Code sections 11165 – 11165.1 provides for the Controlled Substances Utilization Review and Evaluation System (CURES), administered by the DOJ, to provide for monitoring of the prescribing and dispensing of Schedule II, III and IV controlled substances. Upon dispensing of a controlled substance in Schedules II – IV, the dispensing pharmacy or clinic must provide dispensing information to the DOJ within a specified time frame. CURES data is utilized by those approved to have access through the DOJ. This data can assist a prescriber or pharmacist to make informed decisions and detect those patients who may be attempting to abuse controlled substances by obtaining multiple prescriptions through various practitioners. The board pays approximately $92,000 annually to help fund the CURES system.

THIS BILL WOULD:
Amend Health and Safety Code sections 11161.5 – 11162.1 to specify additional information that is required of a security printer applicant, to include all levels of persons (i.e., managers, employees, contractors, etc.) that may have access to the controlled substances security forms. Amendments also specify that the fee the DOJ may assess would be sufficient to cover inspection of security printers. The amendments further specify that a security prescription form that is not in compliance with the section shall not be valid after July 1, 2012.

Amend Health and Safety Code section 11165 to specify that only those prescriptions for a schedule II – IV controlled substance, as defined by federal law, will be required to be reported to CURES.

Amend Health and Safety Code section 11165.1 to allow a licensed health care practitioner, who is eligible to prescribe Schedule II, III or IV controlled substances, to apply to the DOJ to obtain approval to electronically access data in the Prescription Drug Monitoring Program and specifies that authorized health care practitioners will only have access to schedule II – IV controlled substances, as defined by federal law.

This bill adds Section 11165.2 to the Health and Safety Code to provide for sanctions and/or penalties of those found to have violated any provision of Chapter 4 of the Health and Safety Code. This section specifies provisions for citations, the assessment and payment of administrative fines, orders of abatement, etc. The provisions allow for a subscriber to request an informal conference regarding any citation or fine; and provides for disciplinary action if fines are not paid within specified time frames.

This bill also adds Section 11165.3 to the Health and Safety Code to specify that the theft or loss of prescription information or forms shall be reported immediately to CURES, no later than three days after the discovery of the loss or theft. The section requires the theft or loss to be reported via (1) the Bureau of Narcotic Enforcement 1175 Reporting Theft/Loss Form or (2) through the CURES PDMP electronic system.

AUTHOR'S INTENT:
According to the author, SB 360 will update the CURES to allow electronic access to the Prescription Drug Monitoring Program (PDMP) launched in 2009. The PDMP provides authorized users, or *"subscribers"* (prescribers, pharmacists, etc.), access to patient controlled substance prescription information in real-time at the point of care – allowing a prescriber or a pharmacist to detect those who may be abusing controlled substances by obtaining multiple prescriptions. Also, this bill would provide safeguards against the theft and fraudulent use of controlled substance prescription pads.

COMMENTS:
Board staff notes some possible challenges with the bill in its current form, most notably the proposed changes to section 11165(d) which would in effect no longer require a pharmacy to transmit data to CURES for items that are only scheduled in California and not at the federal level. The ramification is compromised information available to conduct CA specific schedule narcotic enforcement activity due to a lack of available dispensing data from now on and into the future. (Sometimes items are scheduled at the state level to address a specific issue that is either not an issue at the federal level, or are necessary to address an enforcement issue at the state level.) Similarly, health care practitioners would also only have information on those products as scheduled at the federal level.

The board may wish to considering offering amended language that would require reporting of those prescriptions that are scheduled either at the state or federal level. (A brief review of the CURES data appears that this may be what is occurring currently.) This amendment could address the concerns stated above.

PRIOR BOARD DISCUSSION and ACTION:
During the May Board Meeting, the board briefly discussed this measure and established a "Watch" position. The bill has been amended twice since that time.

This bill was originally intended to add substances that were scheduled at the federal level, but included in the state schedules including:

Amend Health and Safety Code section 11054 – 11057 for the purpose of adding substances to Schedules I through IV, as follows:

Schedules I and II – adds Opiates
Schedule III – Adds depressants, and anabolic steroids and chorionic gonadotropin
Schedule IV – Adds depressants, stimulants

Previous versions of the the bill would also have the following conforming changes (update references) in the following sections:

1. Family Code section 6929 - Defines various terms, including "LAAM." This bill makes a conforming change to a reference to Section 11055 of the Health and Safety Code.
2. Health and Safety Code section 11212 - Cross references substances in Schedule I for the purpose of research, instruction, or analysis.
3. Health and Safety Code section 11350 – 11355 - Updates references to Schedule III, regarding possession / punishment.
4. a. Health and Safety Code section 11377 – Punishment for possession. Updates references to Schedule II related to Ketamine, Cathine and norpseudoephedrine; and
   b. Amends subdivision (a) of HSC 11377 to reference Pharmacy Law (commencing with *4110*, not 4211)
5. Health and Safety Code section 11378 – Cross reference to Schedule III updated

6. Health and Safety Code section 11379-11379.2 – Updates cross references to Pharmacy Law section 4110 and updates cross references to Schedule III. Punishment.
7. Health and Safety Code section 11839.2, 11875 – Updates cross reference to LAAM in Schedule II.

PREVIOUS/RELATED LEGISATION:
Prior to recent amendments, SB 260 (2011, Cannella) contained similar provisions. SB 260 was amended and now addresses provisions related to the reporting of transactions of ephedrine and other specified substances to the Department of Justice.

SB 734 (Torlakson) – Chapter 487, Statutes of 2005. This bill provided clean-up changes to facilitate the effective operation of the CURES, and the program duties of the Bureau of Narcotic Enforcement. The board had a "Oppose unless amended" position on the measure.

SB 1071 (DeSaulnier). 2010. This bill would have imposed a tax on every manufacturer and importer of a controlled substance specified in Schedules II, III or IV to secure funding for providing Patient Activity Reports (CURES data) to all practitioners and those who dispense controlled substances. The board did not take a position on the bill, which died in committee.

FISCAL IMPACT:
The enforcement of these provisions resides primarily with the Department of Justice. The board does not anticipate any significant impact. Minor impact to board operations could be absorbed within existing resources.

SUPPORT/OPPOSITION:
Support
Department of Justice (Sponsor)
California Narcotic Officers' Association
California Peace Officers' Association
California Police Chiefs Association
California State Sheriffs' Association
California Statewide Law Enforcement Association
Consumer Attorneys of California
Peace Officers Research Association of California

Opposition
None

HISTORY:

Date	Action
July 7	Read second time and amended. Re-referred to Com. on APPR.
July 6	From committee: Do pass as amended and re-refer to Com. on APPR.with recommendation: To consent calendar. (Ayes 7. Noes 0.) (July 5).
June 13	Referred to Com. on PUB. S.
June 2	In Assembly. Read first time. Held at Desk.
June 2	Read third time. Passed. (Ayes 39. Noes 0. Page 1282.) Ordered to the Assembly.
May 31	Ordered to special consent calendar.
May 27	Read second time. Ordered to third reading.
May 26	From committee: Do pass. (Ayes 9. Noes 0. Page 1115.) (May 26).
May 25	Set for hearing May 26.
May 23	Placed on APPR. suspense file.
May 13	Set for hearing May 23.
May 10	Read second time and amended. Re-referred to Com. on APPR.
May 9	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 7. Noes 0. Page 862.) (May 3).
Apr. 26	Set for hearing May 3.
Apr. 14	From committee with author's amendments. Read second time and amended. Re-referred to Com. on PUB. S.
Mar. 31	Re-referred to Com. on PUB. S.
Mar. 22	From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.
Feb. 24	Referred to Com. on RLS.
Feb. 16	From printer. May be acted upon on or after March 18.
Feb. 15	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY JUNE 22, 2011

AMENDED IN SENATE MAY 2, 2011

SENATE BILL No. 850

Introduced by Senator Leno

February 18, 2011

An act to amend Section 56.101 of the Civil Code, relating to medical records.

LEGISLATIVE COUNSEL'S DIGEST

SB 850, as amended, Leno. Medical records: confidential information.

The Confidentiality of Medical Information Act requires that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records do so in a manner that preserves the confidentiality of the information contained in the record, and provides that negligence in conducting these activities may result in damages or an administrative fine or civil penalty, as specified.

This bill would require an electronic health or medical record system to automatically record *and preserve* any change or deletion of electronically stored medical information, and would require the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was made to the medical information.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 56.101 of the Civil Code is amended to read:

56.101. (a) Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

(b) *(1)* An electronic health record system or electronic medical record system shall ~~automatically record~~ *do the following:*

(A) Protect and preserve the integrity of electronic medical information.

(B) Automatically record and preserve any change or deletion of any electronically stored medical information. The record of any change or deletion shall include the identity of the person who accessed and changed the medical information, the date and time the medical information was accessed, and the change that was made to the medical information. ~~The record of the change or deletion shall be made part of the patient's medical information, and shall be accessible upon request of a patient or his or her representative to review the medical information.~~

(2) A patient's right to access or receive a copy of his or her electronic medical records upon request shall be consistent with current applicable state and federal laws governing patient access to, and the use and disclosures of, medical information.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 850 **VERSION: As amended June 22, 2011**

AUTHOR: Leno **SPONSOR: Consumer Attorneys of California**

BOARD POSITION: None

SUBJECT: Medical Records: Confidential Information

Affected Sections: Amend Section 56.101 of the Civil Code

CURRENT STATUS: Assembly Appropriations Committee hearing scheduled for August 17, 2011

EXISTING LAW:
1. Requires every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records to do so in a manner that preserves the confidentiality of the information contained therein.
2. Further it specifies that any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

THIS BILL WOULD:
In addition to the above, specify that an electronic medical record system shall do the following:
- Protect and preserve the integrity of the information
- Automatically record and preserve any changes to the record, including the person that made the change as specified
- Clarify that a patient's access to electronic medical records is consistent with current state and federal law.

AUTHOR'S INTENT:
The sponsor of this bill states that this bill will help to prevent medical errors and improve the quality of patient care "by ensuring that electronic medical records accurately reflect a patient's medical treatment and history, by preserving a record of any modification or deletion made to a patient's medical record."

FISCAL IMPACT:
The board does not anticipate any significant impact to board operations. Any minimal impact could be addressed within existing resources.

SUPPORT/OPPOSITION:

Support

Consumer Attorneys of California (sponsor)
California Association of Health Underwriters
Consumer Federation of California

Opposition

None

HISTORY:

Date	Action
June 28	From committee: Do pass and re-refer to Com. on APPR. (Ayes 7. Noes 2.) (June 27). Re-referred to Com. on APPR.
June 22	From committee with author's amendments. Read second time and amended. Re-referred to Com. on JUD.
June 22	From committee: Do pass and re-refer to Com. on JUD. (Ayes 14. Noes 0.) (June 21). Re-referred to Com. on JUD.
June 9	Referred to Coms. on HEALTH and JUD.
June 1	In Assembly. Read first time. Held at Desk.
May 31	Read third time. Passed. (Ayes 21. Noes 15. Page 1178.) Ordered to the Assembly.
May 12	Read second time. Ordered to third reading.
May 11	From committee: Do pass. (Ayes 3. Noes 2. Page 951.) (May 10).
May 2	From committee with author's amendments. Read second time and amended. Re-referred to Com. on JUD.
Apr. 29	Set for hearing May 10.
Mar. 10	Referred to Com. on JUD.
Feb. 20	From printer. May be acted upon on or after March 22.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY JUNE 21, 2011

AMENDED IN SENATE APRIL 13, 2011

SENATE BILL No. 541

Introduced by Senator Price

February 17, 2011

An act to add Section 40 to the Business and Professions Code, relating to ~~profession~~ *professions* and vocations, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 541, as amended, Price. ~~Contractors' State License~~ Regulatory boards: expert consultants.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law, the Chiropractic Act, enacted by initiative, provides for the licensure and regulation of chiropractors by the State Board of Chiropractic Examiners. Existing law, the Osteopathic Act, requires the Osteopathic Medical Board of California to regulate osteopathic physicians and surgeons. Existing law generally requires applicants for a license to pass an examination and authorizes boards to take disciplinary action against licensees for violations of law. Existing law establishes standards relating to personal service contracts in state employment.

This bill would authorize these boards to enter into an agreement with an expert consultant, subject to the standards regarding personal service contracts described above, to provide enforcement and examination assistance. The bill would require each board to establish policies and procedures for the selection and use of these consultants.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 40 is added to the Business and Professions Code, to read:

40. (a) Subject to the standards described in Section 19130 of the Government Code, any board, as defined in Section 22, the State Board of Chiropractic Examiners, or the Osteopathic Medical Board of California may enter into an agreement with an expert consultant to do any of the following:

(1) Provide an expert opinion on enforcement-related matters, including providing testimony at an administrative hearing.

(2) Assist the board as a subject matter expert in examination development, examination validation, or occupational analyses.

(3) Evaluate the mental or physical health of a licensee or an applicant for a license as may be necessary to protect the public health and safety.

(b) An executed contract between a board and an expert consultant shall be exempt from the provisions of Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(c) Each board shall establish policies and procedures for the selection and use of expert consultants.

(d) Nothing in this section shall be construed to expand the scope of practice of an expert consultant providing services pursuant to this section.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

To ensure that licensees engaging in certain professions and vocations are adequately regulated at the earliest possible time in order to protect and safeguard consumers and the public in this state, it is necessary that this act take effect immediately.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 541 **VERSION: As Amended June 21, 2011**

AUTHOR: Price **SPONSOR: Author**

BOARD POSITION: Support

SUBJECT: Regulatory Boards: Expert Consultants

Affected Sections: Add Section 40 to the Business and Professions Code

Current Status: Assembly Appropriations Committee hearing scheduled for August 17, 2011

EXISTING LAW:

1. Business and Professions Code section 157 allows the director, at the request of and with the consent of a board, to enter into a contract on behalf of the board.
2. Business and Professions Code section 307 allows the director to contract for services of experts and consultants where necessary.

THIS BILL WOULD:

1. Authorize the board to enter into an agreement with an expert consultant and would specify that an executed contract between the board and an expert is exempt from the Public Contract Code.
2. Require the board to establish policies and procedures for the selection of experts.
3. Specify that nothing in these provisions are intended to expand the scope of practice of an expert performing a service.

AUTHOR'S INTENT:

This measure will ensure that licensees engaging in certain professions and vocations are adequately regulated at the earliest possible time in order to protect and safeguard consumers and the public in this state.

COMMENTS:

This bill contains an urgency provision which will allow this measure to take effect immediately.

This proposal will aid the board in meeting its consumer protection mandate by ensuring the board has the ability to quickly enter into an agreement with an expert in disciplinary matters. Further, this proposal will ensure that the board can timely and efficiently contract with experts whose services are needed to develop the pharmacist licensure exam.

PRIOR BOARD DISCUSSION and ACTION:
During the May Board Meeting, the board discussed this measure and its benefits. The board established a "Support" position on this measure. Board staff advised the author's office verbally and in writing.

This measure was amended since the board meeting to specify that the scope of practice of the expert cannot be expanded.

FISCAL/ECONOMIC IMPACT:
Board staff does not anticipate any significant impact to board operations or funds.

SUPPORT/OPPOSITION:
Support
Medical Board of California (co-sponsor)
Contractors State License Board (co-sponsor)
Board of Barbering and Cosmetology
Board of Behavioral Sciences
Board of Optometry
Board of Pharmacy
Board of Podiatric Medicine
Board of Psychology
Board of Registered Nursing
Board of Vocational Nursing and Psychiatric Technicians
California Board of Accountancy
California State Pipe Trades Council
Court Reporters Board of California
Dental Board of California
International Brotherhood of Electrical Workers
Physician Assistant Committee
Respiratory Care Board of California
State Board of Guide Dogs for the Blind
Western States Council of Sheet Metal Workers

Opposition
None of file

HISTORY:

Date	Action
June 28	From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (June 28). Re-referred to Com. on APPR.
June 21	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & C.P.
June 2	Referred to Com. on B., P. & C.P.
May 23	In Assembly. Read first time. Held at Desk.
May 23	Read third time. Urgency clause adopted. Passed. (Ayes 39. Noes 0.Page 1065.) Ordered to the Assembly.
May 18	Read second time. Ordered to third reading. Ordered to special consent calendar.
May 17	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
May 6	Set for hearing May 16.
May 3	From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0. Page 848.) (May 2). Re-referred to Com. on APPR.
Apr. 13	From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.
Apr. 12	Set for hearing May 2.
Apr. 11	Hearing postponed by committee.
Apr. 4	Set for hearing April 25.
Mar. 3	Referred to Com. on B., P. & E.D.
Feb. 18	From printer. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY MARCH 30, 2011

AMENDED IN ASSEMBLY MARCH 15, 2011

AMENDED IN ASSEMBLY MARCH 7, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 389

Introduced by Assembly Member Mitchell
(Principal coauthor: Senator Pavley)

February 14, 2011

~~An act to amend Section 2191 of the Business and Professions Code, and~~ *An act* to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce these provisions.

~~Existing law requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons.~~

~~This bill would require the division to consider including a course on bleeding disorders, as specified, in determining its continuing education requirements.~~

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

~~SECTION 1. Section 2191 of the Business and Professions Code is amended to read:~~

~~2191. (a) In determining its continuing education requirements, the Division of Licensing shall consider including a course in human sexuality as defined in Section 2090 and nutrition to be taken by those licensees whose practices may require knowledge in those areas.~~

~~(b) The division shall consider including a course in child abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected children.~~

~~(c) The division shall consider including a course in acupuncture to be taken by those licensees whose practices may require knowledge in the area of acupuncture and whose education has not included instruction in acupuncture.~~

~~(d) The division shall encourage every physician and surgeon to take nutrition as part of his or her continuing education, particularly a physician and surgeon involved in primary care.~~

~~(e) The division shall consider including a course in elder abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected persons 65 years of age and older.~~

~~(f) In determining its continuing education requirements, the division shall consider including a course in the early detection and treatment of substance abusing pregnant women to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these women.~~

~~(g) In determining its continuing education requirements, the division shall consider including a course in the special care needs of drug addicted infants to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these infants.~~

~~(h) In determining its continuing education requirements, the division shall consider including a course providing training and guidelines on how to routinely screen for signs exhibited by abused women, particularly for physicians and surgeons in emergency, surgical, primary care, pediatric, prenatal, and mental health settings. In the event the division establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.~~

~~(i) In determining its continuing education requirements, the division shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:~~

~~(1) Pain and symptom management.~~

~~(2) The psychosocial dynamics of death.~~

~~(3) Dying and bereavement.~~

~~(4) Hospice care.~~

~~(j) In determining its continuation education requirements, the division shall give its highest priority to considering a course on pain management.~~

~~(k) In determining its continuing education requirements, the division shall consider including a course on bleeding disorders, with particular emphasis on von Willebrand disease using the latest treatment guidelines adopted by the National Heart, Lung, and Blood Institute.~~

~~SEC. 2.~~

SECTION 1. Article 5 (commencing with Section 125286.10) is added to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.10. This article shall be known, and may be cited, as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.15. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Von Willebrand disease is a human bleeding disorder caused by a hereditary deficiency or abnormality of the von Willebrand factor in human blood, which is a protein that helps clot blood. Von Willebrand disease is a chronic, lifelong, incurable, but treatable, disease affecting at least 360,000 Californians.

(c) Until the 1970s, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors has provided people with hemophilia and other bleeding disorders the opportunity to lead normal lives, free of pain and crippling arthritis.

(d) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(e) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California.

(f) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations according to the federal Centers for Disease Control and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(g) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped Persons Program, the California Children's Services Program, and the Medi-Cal program.

(h) For the benefit of persons with hemophilia or other bleeding disorders, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.20. Unless the context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(b) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(c) "Bleeding disorder" means a medical condition characterized by a deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that, without treatment, result in uncontrollable bleeding or abnormal blood clotting.

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) "Emergency" means care as defined in Section 1317.1.

(f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the Factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

(g) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding specifically for the treatment of patients with bleeding disorders from federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and

Services Administration (HRSA) of the United States Department of Health and Human Services.

(h) "Home nursing services" means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.

(i) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center or other clinical setting. Places where home use occurs include, without limitation, a home or other nonclinical setting.

(j) "Patient" means a person needing a blood clotting product for home use.

(k) (1) "Provider of blood clotting products for home use" means all the following pharmacies, except as described in Section 125286.35, that dispense blood clotting factors for home use:

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision may also provide home nursing services for persons with bleeding disorders.

(3) The providers described in this subdivision shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.

125286.25. Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors.

(c) Maintain 24-hour on-call service seven days a week for every day of the year, adequately screen telephone calls for emergencies, acknowledge all telephone calls within one hour or less, and have access to knowledgeable pharmacy staffing on call 24 hours a day, to initiate emergency requests for clotting factors.

(d) Have the ability to obtain all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained.

(e) Supply all necessary ancillary infusion equipment and supplies with each prescription, as needed.

(f) Store and ship, or otherwise deliver, all blood clotting products in conformity with all state and federally mandated standards, including, but not limited to, the standards set forth in the product's approved package insert (PI).

(g) When home nursing services are necessary, as determined by the treating physician, provide these services either directly or through a qualified third party with experience in treating bleeding disorders and coordinate pharmacy services with the third party when one is used to provide home nursing services.

(h) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(i) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, medications, and home nursing services to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(j) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(k) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(*l*) Provide language interpretive services over the telephone or in person, as needed by the patient.

(m) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(n) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

(o) Comply with the privacy and confidentiality requirements of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.30. The California State Board of Pharmacy shall administer and enforce this article.

125286.35. Nothing in this article shall apply to either hospital pharmacies or health system pharmacies that dispense blood clotting products due only to emergency, urgent care, or inpatient encounters, or if an inpatient is discharged with a supply of blood clotting products for home use.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 389 **VERSION: As Amended March 30, 2011**

AUTHOR: Mitchell **SPONSOR: Hemophilia Council of California**

BOARD POSITION: Watch

SUBJECT: Bleeding disorders: Blood Clotting Products

Affected Sections: Amend Section 2191 of the Business and Professions Code and Add Article 5 (commencing with Section 125286.10) to Chapter 2 or Part 5 of Division 106 of the Health and Safety Code

Current Status: Senate Appropriation Committee hearing scheduled for August 15, 2011

EXISTING LAW:

1. Establishes the Holden-Moscone-Garamendi Genetically Handicapped Person's Program within the Department of Health Care Services. [HSC §125125]
2. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically disabling conditions, including hemophilia. [HSC §125130]
3. Requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons as specified and sets forth the criteria that the division shall use in considering courses. [B&PC §2191]

THIS BILL WOULD:

1. Require the division to consider including a course on bleeding disorders with particular emphasis on von Willebrand disease using the latest treatment guidelines adopted by the National Heart, Lung and Blood Institute.
2. Add Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act that includes the following:
    a. Findings and declarations about bleeding disorders, history of and treatment of such disorders, pharmacies role in the delivery of products, identification of persons eligible for treatment through various programs, and states that this article is necessary for the benefit of persons with bleeding disorders to establish standards of service and to promote cost effective, life saving products for home use.
    b. Defines various terms for purposes of this article including:

i. “home nursing services” means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.
ii. “provider of blood clotting products for home use” means hospital pharmacies, health systems pharmacies, pharmacies affiliated with treatment centers, specialty home care pharmacies and retail pharmacies. These providers are allowed to provide home nursing services and are required to include a health care service plan and all its affiliated providers if the plan exclusively contracts with a single medication group in a specified areas to provide professional services to enrollees.

c. Requires that each provider, as defined above, meet the following requirements:
i. Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescriber and ensure quality care.
ii. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of product on hand as well and understanding about proper storage and refrigeration.
iii. Maintain 24-hour on-call service seven days a week, 365 days a years.
iv. Have the ability to obtain all brands of the products approved by the FDA in multiple assay ranges as specified.
v. Supply all necessary ancillary infusion equipment and supplies as needed.
vi. Store, ship, or otherwise deliver, all products in conformity with state and federally mandated standards.
vii. Provide home nursing services either directly or via a third party, when determined necessary by the physician.
viii. Ship product within two business days to a patient for a nonemergency prescription.
ix. For emergencies, deliver products, equipment, medications and home nursing services within 12 hours, for patients living within 100 miles of a major metropolitan airport, or within one days for patients living outside that area.
x. Provide contact information to a patient to report problems with delivery.
xi. Provide patient with product recall and withdrawal notifications within 24 hours.
xii. Provide language interpretive service via phone or in person, as needed.
xiii. Have a detailed plan in the event of a natural or manmade disaster.
xiv. Provide appropriate record keeping.
xv. Comply with HIPAA requirements.

d. Requires the California Board of Pharmacy to administer and enforce this article.

AUTHOR'S INTENT:
According to the author's office, "AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, von Willebrand disease and other bleeding disorders."

COMMENTS:
Many of these provisions are currently the standard of practice, but are not mandated anywhere. This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received. The board would already have jurisdiction to investigate consumer complaints involving poor service or product delivery that resulted in either patient harm or the potential for harm. We are unaware of any such complaints received by the board.

There are potential challenges in enforcing some of these provisions. Specifically, the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting factor on hand as required. Further, it is unclear if the board would have jurisdiction over the home nursing services and the quality of the care provided.

The previous version of this bill contained a provision requiring the Licensing Division of the Medical Board to consider requiring a continuing education course on bleeding disorders. This provision was amended out of the measure on March 30, 2011.

PRIOR BOARD DISCUSSION and ACTION:
During the May Board Meeting, the board briefly discussed this measure and established a "watch" position on the measure.

FISCAL/ECONOMIC IMPACT:
We anticipate a portion of an inspector PY will be necessary to ensure compliance with these provisions. This workload could possibly be absorbed if the board is able to fill all authorized inspector positions. However, because of the bill's specificity and the need for close monitoring of these provisions, the board would need to do frequent inspections. Because the specialty pharmacies are not required to have a separate license, nor are they required to notify the board that they provide such services, performing inspection on all pharmacies that provide these services would be a challenge.

PREVIOUS/RELATED LEGISLATION

SB 1594 (Steinberg, 2007) would have established standards for providers of blood clotting products. The board had a "Watch" position on the bill. The measure later died after being placed on the Senate Appropriations Suspense File and never passed out of the house of origin.

SB 971 (Pavely, 2010) introduced legislation similar to this proposal. The board did not have a position on this bill. This bill was vetoed by the governor.

> "I am returning Senate Bill 971 without my signature. This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address. For these reasons, I am unable to sign this bill."

SUPPORT/OPPOSITION:

Support

Baxter Healthcare
California Medical Association
California Pharmacists Association
Community Healthcare Services
CSL Behring
Federal Hemophilia Treatment Centers, Region IX
Grifols Inc.
Hemophilia Council of California
Hemophilia Foundation of Northern California
Herndon Pharmacy
Hueneme Family Pharmacy
Meyer Family Cellars
National Cornerstone Healthcare Services Inc.
Pfizer Inc.
Plasma Protein Therapeutics Association
Talecris Biotherapeutics
UCD Hemophilia Treatment Center
Walgreens
Two individuals

Oppose

None

HISTORY:

July 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (July 6). Re-referred to Com. on APPR.

June 23 From committee: Do pass and re-refer to Com. on B., P. & E.D. with recommendation: to consent calendar. (Ayes 8. Noes 0.) (June 22). Re-referred to Com. on B.,P. & E.D.
June 8 In committee: Hearing postponed by committee.
May 12 Referred to Coms. on HEALTH and B., P. & E.D.
Apr. 28 In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 28 Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 1127.)
Apr. 14 Read second time. Ordered to third reading.
Apr. 13 From committee: Do pass. (Ayes 12. Noes 3.) (April 13).
Apr. 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 15. Noes 3.) (April 5). Re-referred to Com. on APPR.
Mar. 31 Re-referred to Com. on HEALTH.
Mar. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 22 From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 9. Noes 0.) (March 22). Re-referred to Com. on HEALTH.
Mar. 16 Re-referred to Com. on B., P. & C.P.
Mar. 15 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Mar. 8 Re-referred to Com. on B., P. & C.P.
Mar. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Feb. 24 Referred to Com. on B., P. & C.P.
Feb. 15 From printer. May be heard in committee March 17.
Feb. 14 Read first time. To print.

AMENDED IN SENATE JULY 14, 2011

AMENDED IN ASSEMBLY APRIL 5, 2011

AMENDED IN ASSEMBLY MARCH 17, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 604

Introduced by Assembly Member Skinner
(Coauthor: Assembly Member Blumenfield)

February 16, 2011

An act to amend, *repeal*, *and add* Sections 121349, 121349.1, 121349.2, and 121349.3 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 604, as amended, Skinner. Needle exchange programs.

Existing law, with certain exceptions, makes it a misdemeanor for a person to deliver, furnish, or transfer, or possess with intent to deliver, furnish, or transfer drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used to introduce into the human body a controlled substance. Existing law provides an exception to this general rule by authorizing a city, county, or city and county to conduct a clean needle and syringe exchange project authorized by the public entity to combat the spread of HIV and bloodborne hepatitis. Existing law exempts providers participating in an exchange project from criminal prosecution for possession of needles or syringes during participation in the project. Existing law also provides a specified annual comment and reporting process relating to the needle and syringe exchange projects.

This bill would, *until January 1, 2019,* authorize the State Department of Public Health to authorize, as specified, certain entities to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. The bill would, *until January 1, 2019,* require the department to establish and maintain on its Internet Web site the address and contact information of these programs.

This bill would, *until January 1, 2019,* exempt staff and volunteers participating in an authorized exchange project from criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project and would exempt program participants from criminal prosecution for possession of needles and syringes acquired from an authorized exchange project entity. The bill would also, *until January 1, 2019,* make the comment and reporting process for the projects biennial.

This bill would make additional technical and nonsubstantive changes.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 121349 of the Health and Safety Code is amended to read:

121349. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of

that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state and federal standards, including those of the United States Public Health Service, in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, all of the following services:

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

(A) Provide needles and syringe exchange services for all of its participants.

(B) Provide HIV and viral hepatitis prevention education services for all of its participants.

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

(A) The total number of persons served.

(B) The total number of syringes and needles distributed, recovered, and disposed of.

(C) The total numbers and types of referrals to drug treatment and other services.

(5) If the application is provisionally deemed appropriate by the department, the department shall, at least 45 days prior to approval of the application, provide for a period of public comment as follows:

(A) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.

(B) Send a written and an e-mail notice to the local health officer of the affected jurisdiction.

(e) The department shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.

(f) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(g) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

SEC. 1.5. Section 121349 is added to the Health and Safety Code, to read:

121349. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(d) This section shall become operative on January 1, 2019.

SEC. 2. Section 121349.1 of the Health and Safety Code is amended to read:

121349.1. *(a)* The State Department of Public Health or a city, county, or a city and county with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Public Health Service, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes acquired from an authorized needle and syringe exchange project entity.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed

SEC. 2.5. Section 121349.1 is added to the Health and Safety Code, to read:

121349.1. (a) A city, county, or a city and county, with or without a health department, that acts to authorize a clean needle

and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Public Health Service, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Providers participating in an exchange project authorized by the county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for possession of needles or syringes during participation in an exchange project.

(b) This section shall become operative on January 1, 2019.

SEC. 3. Section 121349.2 of the Health and Safety Code is amended to read:

121349.2. *(a)* Local government, local health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

SEC. 3.5. Section 121349.2 is added to the Health and Safety Code, to read:

121349.2. (a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on an annual basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become operative on January 1, 2019.

SEC. 4. Section 121349.3 of the Health and Safety Code is amended to read:

121349.3. *(a)* The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with

needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this biennial meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of that local health officer.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

SEC. 5. Section 121349.3 is added to the Health and Safety Code, to read:

121349.3. (a) The health officer of the participating jurisdiction shall present annually at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate.

(b) This section shall become operative on January 1, 2019.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 604 **VERSION: As Amended July 14, 2011**

AUTHOR: Skinner **SPONSOR: Drug Policy Alliance**

BOARD POSITION: Support

SUBJECT: Needle exchange programs.

Affected Sections: An act to amend Sections 121349, 121349.1, 121349.2, and 121349.3 of the Health and Safety Code

CURRENT STATUS: Assembly Third Reading

EXISTING LAW:

Health and Safety Code Section 121349

1. Sets for legislative findings and declarations about needle exchange programs (NEPs).
2. Authorizes a clean needle and syringe exchange project in any city and county as specified.

Health and Safety Code Section 121349.1

Requires a city or county that approves such a project shall, in consultation with the State Department of Public Health, authorize the exchange of clean needles and syringes under conditions as specified.

Health and Safety Code Section 121349.2

Provides for an opportunity to comment on such a program on an annual basis.

Health and Safety Code Section 121349.3

1. Requires that the health officer of the participating jurisdiction shall present annually at an open meeting of the board of supervisors or city council a report detailing the program including, relevant statistics on blood-borne infections associated with needle sharing activity and the use of public funds for these programs.
2. Specifies that law enforcement, other stakeholders and the public be provided ample opportunity to provide comment during this meeting.

THIS BILL WOULD:

1. Allow the California Department of Public Health, until January 1, 2019, to also authorize NEPs, consistent with state and federal standards, and set for the application criteria.
2. Require the department to hold a public meeting at least 45 days prior to approving the program, as specified.
3. Clarify that the California Department of Public Health, a city, county or a city and county, with or without a department pf public health department, may provide an NEP pursuant to appropriate authorizations. Also specifies that program participants shall not be subject to criminal prosecution for possession.
4. Would require an opportunity for public comment on any city or county program on a biennial basis.
5. Would require the health officer to present on a biennial basis, a report detailing the program relevant statistics on *bloodborne* infections associated with needle sharing activity and the use of public funds for these programs, either to the city or county, or to the department.

AUTHOR'S INTENT:

The author notes that the state lacks the authority to respond to urgent public health and fiscal concerns in parts of the state. Counties without a syringe exchange are amongst the counties with the highest number of AIDS cases related to syringe sharing, and with the highest per capita rate of AIDS from syringe sharing.

PRIOR BOARD DISCUSSION and ACTION

During the May Board Meeting, the board discussed the measure and established a "Support" position. Board staff provided a letter of support following the meeting.

This bill was amended to include a December 18, 2018 sunset date on its provisions. After that time, the law would return to its current form.

FISCAL/ECONOMIC IMPACT:

The bill does not have any significant fiscal impact to the board.

PREVIOUS/RELATED LEGISLATION:

SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 - Furnishing Hypodermic Needles and Syringes Without Prescription authorized until December 31, 2010, a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term

desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required. The board had a support position on this bill.

SB 774 (Vasconcellos, 2005) would have authorized a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription as specified. The board supported this bill; however it was vetoed by the governor.

SB 1305 (Figueroa) Chapter 64, Statutes of 2006, prohibited a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

AB 110 (Laird), Chapter 707, Statutes of 2007, permits a public entity that receives General Fund money from the Department of Health Services (now DPH) for HIV prevention and education to use that money to support needle exchange programs. The board had a support position on this bill.

AB 1701 (Chesbro, Chapter 667, Statutes of 2010), extended the Disease Prevention Demonstration Project (DPDP) until December 31, 2018, which permits cities or counties to authorize licensed pharmacists to sell or furnish 10 or fewer hypodermic needles or syringes to a person for use without a prescription, as specified. This will was signed by the governor.

AB 1858 (Blumenfield, 2010) would have allowed the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes. This bill was vetoed by the governor.

> "I am returning Assembly Bill 1858 without my signature. I signed legislation in 2005 that reflected a careful balance between good public health policy and local decision-making authority. I remain comfortable with that original decision and do not believe it is appropriate to change this balance and instead give authority to the state Department of Public Health to overrule local decisions regarding syringe exchange programs. For this reason, I am unwilling to sign this bill."

SB 1029 (Yee, 2010) contained many of the same provisions. The governor vetoed this measure.

> "I am returning Senate Bill 1029 without my signature. When I signed legislation my first year in office allowing for a pilot program to allow the sale of syringes through participating counties and registered pharmacies, I was seeking to balance the competing public health, law enforcement and local control issues that this issue requires. I believe this balance was achieved and SB 1029 would remove the ability of local officials to best determine policies in their jurisdiction. Some counties have not

sought to implement this pilot program, citing competing priorities, lack of pharmacy interest and law enforcement opposition. I respect these local decisions and while I appreciate the author's hard work and dedication to this issue, I cannot sign this bill."

SUPPORT/OPPOSITION:

Support

Drug Policy Alliance (sponsor)
AIDS Project Los Angeles
American Civil Liberties Union
American Nurses Association California
California Association of Alcohol and Drug Program Executives, Inc.
California Hepatitis Alliance
California Nurses Association
California Opioid Maintenance Providers
California Society of Addiction Medicine
California State Board of Pharmacy
California Syringe Exchange Provider Network
Center for Health Justice
Clinica Monsenor Oscar A. Romero
Common Ground: The Westside HIV Community Center
County Alcohol and Drug Program Administrators Association of California
Harm Reduction Coalition
L.A. Gay and Lesbian Center
National Association of Social Workers
Redwood AIDS Information Network and Services
Saint James Infirmary
San Francisco AIDS Foundation
San Francisco Hepatitis C Task Force
Santa Clara County Board of Supervisors
Waste Management

Oppose

California Narcotic Officers' Association
California Police Chiefs Association
International Faith Based Coalition
League of California Cities
Los Angeles Division, League of California Cities

HISTORY:

Date	Action
July 14	Read second time and amended. Ordered to third reading.
July 13	From committee: Do pass as amended. (Ayes 6. Noes 3.) (July 11).

June 23 From committee: Do pass and re-refer to Com. on APPR. (Ayes 5. Noes 3.) (June 22). Re-referred to Com. on APPR.
June 8 In committee: Hearing postponed by committee.
May 26 Referred to Com. on HEALTH.
May 16 In Senate. Read first time. To Com. on RLS. for assignment.
May 16 Read third time. Passed. Ordered to the Senate. (Ayes 52. Noes 26. Page 1386.)
Apr. 14 Read second time. Ordered to third reading.
Apr. 13 From committee: Do pass. (Ayes 12. Noes 3.) (April 13).
Apr. 6 Re-referred to Com. on APPR.
Apr. 5 Read second time and amended.
Apr. 4 From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 13. Noes 6.) (March 29).
Mar. 21 Re-referred to Com. on HEALTH.
Mar. 17 Referred to Com. on HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 17 From printer. May be heard in committee March 19.
Feb. 16 Read first time. To print.

AMENDED IN ASSEMBLY JUNE 28, 2011

AMENDED IN SENATE MAY 24, 2011

AMENDED IN SENATE MAY 9, 2011

SENATE BILL No. 41

Introduced by Senator Yee

December 7, 2010

An act to add and repeal Sections 4144.5, 4145.5, and 4148.5 of, and to repeal Section 4140 of, the Business and Professions Code, and to add Section 121281 to, and to add and repeal Section ~~11364.5~~ *11364.1* of, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 41, as amended, Yee. Hypodermic needles and syringes.

Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes, and requires, with certain exceptions, a prescription to purchase a hypodermic needle or syringe for human use. Existing law prohibits any person from possessing or having under his or her control any hypodermic needle or syringe, except in accordance with those regulatory provisions.

This bill would delete the prohibition against any person possessing or having under his or her control any hypodermic needle or syringe, except in accordance with the aforementioned regulatory provisions.

Existing law, beginning January 1, 2011, and ending December 31, 2018, authorizes a county or city to authorize a licensed pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person 18 years of age or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with a local health department in the Disease Prevention Demonstration Project, established

by law to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of bloodborne pathogens, including HIV and hepatitis C.

Under existing law, it is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking specified controlled substances.

Existing law, beginning January 1, 2011, and ending December 31, 2018, provides that the above-described provisions, pursuant to authorization from a city or county, shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes.

This bill would, until January 1, 2015, make these provisions, including any local authorization, inoperative, and would in the interim, authorize a physician or pharmacist, without a prescription or a permit, to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older and would authorize a person 18 years of age or older, without a prescription or license, to obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

This bill would, until January 1, 2015, provide that the above-described provisions making it unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia for unlawfully injecting or smoking certain controlled substances shall not apply to possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

This bill would require the state Office of AIDS to develop and maintain information on its Internet Web site to educate consumers at risk of bloodborne infections of opportunities to improve and protect their health, and to protect the public health and would also require the California State Board of Pharmacy to post, or post a link to, this information on its Internet Web site.

The Pharmacy Law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes. Existing law makes it a crime to knowingly violate any provision relating to the Pharmacy Law.

This bill would, until January 1, 2015, require pharmacies that furnish nonprescription hypodermic needles and syringes to store the

hypodermic needles and syringes in a manner that ensures that they are not accessible to unauthorized persons, and would require pharmacies or hypodermic needle and syringe exchange programs to provide consumers with prescribed options for consumer disposal of hypodermic needles and syringes. This bill would also, until January 1, 2015, require the pharmacies to provide prescribed written information or verbal counseling at the time of furnishing or sale of nonprescription hypodermic needles or syringes. By changing the definition of an existing crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. It is the intent of the Legislature to improve access to syringes and hypodermic needles so as to remove significant barriers for persons seeking to protect their health and the health of other persons, and to remove barriers for programs or businesses to provide sterile injection equipment and education to adults, thereby reducing the spread of communicable diseases and protecting the public health.

SEC. 2. Section 4140 of the Business and Professions Code is repealed.

SEC. 3. Section 4144.5 is added to the Business and Professions Code, to read:

4144.5. (a) A person may sell or obtain hypodermic needles and hypodermic syringes without a prescription or permit, for uses that the board determines are industrial, and that person shall not be required to comply with Section 4145.5 or 4146.

(b) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

SEC. 4. Section 4145.5 is added to the Business and Professions Code, to read:

4145.5. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program.

(2) It shall furnish, or make available, mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a personal medical sharps disposal container that meets applicable state and federal standards for disposal of medical sharps waste.

(f) A pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

(g) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

SEC. 5. Section 4148.5 is added to the Business and Professions Code, to read:

4148.5. (a) All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144, or 4145.5, or under Section 11364.5, 121349, or 121349.1 of the Health and Safety Code.

(b) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

SEC. 6. Section ~~11364.5~~ *11364.1* is added to the Health and Safety Code, to read:

~~11364.5.~~

11364.1. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of 30 or fewer hypodermic needles or syringes if acquired from a physician, pharmacist, hypodermic needle and syringe exchange program, or any other source that is authorized by law to provide sterile syringes or hypodermic needles without a prescription.

(d) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

SEC. 7. Section 121281 is added to the Health and Safety Code, to read:

121281. In order to assist pharmacists and pharmacy personnel in the education of consumers who are at risk of bloodborne infections regarding methods and opportunities for improving and protecting their health, and thereby protect the public health, the Office of AIDS shall develop and maintain all of the following information, on its Internet Web site, and the California State Board of Pharmacy shall also post, or maintain a link to, the information on its Internet Web site:

(a) How consumers can access testing and treatment for HIV and viral hepatitis.

(b) How consumers can safely dispose of syringes and hypodermic needles or other sharps waste.

(c) How consumers can access drug treatment.

SEC. 8. (a) Sections 4144, 4145, and 4148 of the Business and Professions Code, and Sections 11364 and 121285 of the Health and Safety Code, including related local authorizations, shall become inoperative until January 1, 2015.

(b) On and after January 1, 2015, Sections 4144, 4145, and 4148 of the Business and Professions Code, and Sections 11364 and 121285 of the Health and Safety Code, shall be operative, including

related local authorization unless the county or city acts to remove the authorization.

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 41 **VERSION: As Amended June 28, 2011**

AUTHOR: Yee **SPONSOR: San Francisco Aids Foundation**
Drug Policy Alliance

BOARD POSITION: Support If Amended

SUBJECT: Hypodermic Needles and Syringes

Affected Sections: Add and repeal Sections 4144.5, 4145.5, 4148.5 and repeal Section 4140 of the Business and Professions Code and add Section 121218 to and add and repeal Section 11364.1 of the Health and Safety Code

CURRENT STATUS: Senate Health Committee Hearing April 6, 2011

EXISTING LAW:

1. Allows a pharmacist, if authorized by a county or city, to furnish or sell 10 or fewer hypodermic needles or syringes at any one time as specified.
2. Establishes a December 31, 2018 sunset date for this provision.
3. Specified that no person shall possess a hypodermic needle or syringe except when acquired in accordance with specified provisions of the law.
4. Allows a pharmacist or physician to furnish hypodermic needles or syringes for human use without a prescription or permit if the person is known to the furnisher and the furnisher has been previously provided with a prescription or proof of legitimate medical need.
5. Establishes the Disease Prevention Demonstration Project (DPDP) as collaboration between pharmacies and local and state health officials for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.
6. Allows for a person to possess, for personal use, 10 or fewer hypodermic needles and syringes if acquired from an authorized source.
7. Allows local governments, local health officers, and law enforcement, the opportunity to comment on needle exchange programs (NEPs) on an annual basis.

THIS BILL WOULD:

1. Repeal the section prohibiting a person from possessing a hypodermic needle or syringe except as provided in Article 9 (Hypodermic Needles and Syringes).

Would authorize the following until January 1, 2015:

2. Allow a physician or pharmacist to furnish hypodermic needles and syringes, without a prescription, if the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of the legitimate medical need to administer a medicine or treatment.
3. Allow a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use.
4. Specify that pharmacies shall furnish such products in a manner to ensure that they are only available to authorized personnel.
5. Shall provide consumers with disposal options including an onsite collection program or make available mail-back sharps containers or personal medical sharps disposal containers.
6. Shall provide written information or verbal counseling to patients about access to drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste.
7. Specify that all stocks of needles and syringes shall be confiscated if found outside the licensed premises or found not in the possession or control of a person entitled under these provisions.
8. Require Office of Aids to develop and maintain information on its website about accessing drug treatment, accessing HIV and hepatitis screenings and safe disposal of syringe and sharps waste; require the Board to either post or maintain a link to the same information on its Web site.
9. Specifies that it is unlawful to possess an opium pipe or any device as specified, used for unlawfully injecting or smoking controlled substances as specified. Further indicates that this does not apply to the possession for personal use of 30 or few hypodermic needle and syringes obtained consistent with legal requirements.

AUTHOR'S INTENT:

According to the author, the intent of the bill is to improve access to hypodermic needles and syringes in order to remove significant barriers for persons seeking to protect their health and the health of other persons. The author also seeks to remove barriers for programs or businesses to provide sterile injection equipment and education to adults.

FISCAL IMPACT:

The bill does not have any significant fiscal impact to the board. As the measure may impact a licensee or entity under the board's jurisdiction, it is possible that the board may exercise regulatory authority over any related activities within a licensee's scope of

practice or authority. The board could likely utilize existing resources to comply with the posting requirements.

PRIOR BOARD DISCUSSION and ACTION:
During the May Board Meeting, the board discussed this measure as well as the potential unintended consequences if the repeal of the section prohibiting a person from possessing a hypodermic needle or syringe remained in the bill. After discussion the board established a "Support If Amended" position and requested that board staff advise the author's office. Following the meeting board staff conveyed the board's concerns to the author's office.

This measure has been amended three times since the board meeting. In its current form, this measure does include provisions about the unlawful possession of needles unless it is consistent with the provisions. This is established in the Health and Safety Code, not in the Business and Professions Code.

PREVIOUS/CURRENT LEGISLATION:
SB 1159 (Vasconcellos) Chapter 608, Statutes of 2004 - Furnishing Hypodermic Needles and Syringes Without Prescription authorized until December 31, 2010, a pharmacist to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created to evaluate the long-term desirability of allowing licensed pharmacies to sell or furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C. Detailed records of nonprescription sales of hypodermic needles and syringes are no longer required. The board had a support position on this bill.

SB 774 (Vasconcellos, 2005) would have authorized a licensed pharmacist to sell or furnish 30 or fewer hypodermic needles or syringes to a person for human use without a prescription as specified. The board supported this bill; however it was vetoed by the governor.

SB 1305 (Figueroa) Chapter 64, Statutes of 2006, prohibited a person from knowingly placing home-generated sharps waste in commercial and residential solid waste collection containers after September 1, 2008.

AB 110 (Laird), Chapter 707, Statutes of 2007, permits a public entity that receives General Fund money from the Department of Health Services (now DPH) for HIV prevention and education to use that money to support needle exchange programs. The board had a support position on this bill.

AB 1701 (Chesbro, Chapter 667, Statutes of 2010), extended the Disease Prevention Demonstration Project (DPDP) until December 31, 2018, which permits cities or counties to authorize licensed pharmacists to sell or furnish 10 or fewer hypodermic needles or syringes to a person for use without a prescription, as specified. This bill was signed by the governor.

AB 1858 (Blumenfield, 2010) would have allowed the California Department of Public Health to authorize entities to provide hypodermic needle and syringe exchange programs in any location where the department determines conditions exist for the rapid spread of deadly or disabling disease spread through the sharing of unclean hypodermic needles and syringes. This bill was vetoed by the governor.

> "I am returning Assembly Bill 1858 without my signature. I signed legislation in 2005 that reflected a careful balance between good public health policy and local decision-making authority. I remain comfortable with that original decision and do not believe it is appropriate to change this balance and instead give authority to the state Department of Public Health to overrule local decisions regarding syringe exchange programs. For this reason, I am unwilling to sign this bill."

SB 1029 (Yee, 2010) contained many of the same provisions. The governor vetoed this measure.

> "I am returning Senate Bill 1029 without my signature. When I signed legislation my first year in office allowing for a pilot program to allow the sale of syringes through participating counties and registered pharmacies, I was seeking to balance the competing public health, law enforcement and local control issues that this issue requires. I believe this balance was achieved and SB 1029 would remove the ability of local officials to best determine policies in their jurisdiction. Some counties have not sought to implement this pilot program, citing competing priorities, lack of pharmacy interest and law enforcement opposition. I respect these local decisions and while I appreciate the author's hard work and dedication to this issue, I cannot sign this bill."

SUPPORT and OPPOSITION:

<u>Support</u>

Drug Policy Alliance (sponsor)
San Francisco AIDS Foundation (co-sponsor)
ACLU
AFSCME
AIDS Project Los Angeles
Alameda County Board of Supervisors
California Hepatitis Alliance
California Medical Association
California Nurses Association

California Opioid Maintenance Providers
California Pharmacists Association
California Psychiatric Association
California Retailers Association
County Alcohol and Drug Program Administrators Association of California
CVS/Caremark
Drug Policy Alliance
Friends Committee on Legislation of California
Health Officers Association of California
Rite Aid
San Francisco Hepatitis C Task Force
Santa Clara County Board of Supervisors
Walgreens

Oppose

Association of Los Angeles Deputy Sheriffs
California District Attorneys Association

HISTORY:

Date	Action
July 14	Read second time. Ordered to third reading.
July 13	From committee: Do pass. (Ayes 11. Noes 4.) (July 13).
June 28	Read second time and amended. Re-referred to Com. on APPR.
June 27	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 12. Noes 6.) (June 21).
June 9	Referred to Com. on HEALTH.
June 1	In Assembly. Read first time. Held at Desk.
May 31	Read third time. Passed. (Ayes 24. Noes 13. Page 1187.) Ordered to the Assembly.
May 24	Read second time and amended. Ordered to third reading.
May 23	From committee: Be placed on second reading file pursuant to Senate Rule 28.8 and be amended.
May 13	Set for hearing May 23.
May 9	Read second time and amended. Re-referred to Com. on APPR.
May 5	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 5. Noes 1. Page 741.) (April 26).
Apr. 14	Set for hearing April 26.
Apr. 7	From committee: Do pass and re-refer to Com. on PUB. S. (Ayes 5. Noes 3. Page 580.) (April 6). Re-referred to Com. on PUB. S.
Mar. 15	Set for hearing April 6.
Mar. 14	Set, first hearing. Hearing canceled at the request of author.
Mar. 4	Set for hearing March 23.
Jan. 20	Referred to Coms. on HEALTH and PUB. S.
Jan. 3	Read first time.
2010	
Dec. 8	From printer. May be acted upon on or after January 7.
Dec. 7	Introduced. To Com. on RLS. for assignment. To print.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 514 **VERSION: As Amended May 10, 2011**

AUTHOR: Simitian **SPONSOR: Author**

BOARD POSITION: SUPPORT

SUBJECT: Dextromethorphan: sale to minors prohibited

Affected Sections: Add Sections 11110 and 11111 to the Health and Safety Code

CURRENT STATUS: Ordered to Third Reading in the Assembly

EXISTING LAW:

1. Health and Safety Code section 11100 establishes the conditions and reporting requirements for the sale of ephedrine and pseudoephedrine to a person under 18 years of age.
2. Regulates the sale of nonprescription drugs.

THIS BILL WOULD:

1. State that it shall be an infraction (punishable by a fine of up to $250) to sell willfully and knowingly to a person under 18 years of age, an over-the-counter drug, material, compound, mixture, preparation or substance containing dextromethorphan without a prescription.
2. State it shall be prima facie evidence of a violation if the person making the sale does not require and obtain "proof of age" from anyone presumably younger than 25.
    a. Defines "proof of age" as any document issued by a government agency that contains a description or photo and provides the person's date of birth.
3. State it shall be affirmative defense to a violation if the defendant can prove all of the following:
    a. Proof of age was obtained as required
    b. The purchaser provided false representation of his or her age
    c. The appearance of the purchaser would lead an ordinary person to believe the purchaser was at least 18 years old.
    d. The sale was made in good faith based on the information provided.
4. Specify that a retail clerk that fails to obtain proof of age is not guilty of an infraction, subject to civil penalties.

a. State that this does not apply to a retail clerk that is willfully participating in an ongoing criminal conspiracy to violate these provisions.

5. Specify, that if feasible, the retailer selling the product, use a cash register that is equipped with an age-verification feature to monitor age-restricted items which shall be programmed to direct the clerk to request verification of age prior to the sale.

AUTHOR'S INTENT:
The intent of this legislation is to restrict access to dextromethorphan by minors. According to the author's office, Poison Control reports an 850% increase in the number of calls it has received over the last ten years resulting from dextromethorphan. The author's office also stated that one in ten high school students has abused this drug.

FISCAL IMPACT:
The board does not anticipate any significant impact to board operations.

COMMENTS:
The author's office indicated that there are conversations at the federal level about whether to classify dextromethorphan as a scheduled substance.

As amended, the provisions that prohibited an employer to taking action against a clerk that unlawfully sold this product have been removed, and provisions were added regarding the use of a cash register that is equipped with an age-verification feature to monitor age-restricted items if feasible.

PRIOR BOARD DISCUSSION and ACTION:
During the May Board Meeting the board discussed this bill as well as the effects of dextromethorphan and the prevalence of abuse. Based on this discussion the board established a "Support" position which was conveyed to the author's office.

This bill was amended to specify that an infraction of this provision could result in a fine of up to $250.

RELATED/PREVIOUS LEGISLATION:
AB 1853 (Simitian, 2003) would have prohibited the sale, without a prescription, of a nonprescription drug containing dextromethorphan to a minor. This bill died on the inactive file.

SB 307 (Simitian, 2005) contained the same general provisions. This bill was never heard in committee.

SUPPORT/OPPOSITION:

Support

California Chapter of American College of Emergency Physicians
California Peace Officers' Association
California Police Chiefs Association, Inc.
California State Board of Pharmacy
City of Palo Alto Police Department
Consumer Healthcare Products Association
Full Circle Treatment Center
Junior Leagues of California
Palo Alto Police Officers' Association
Rady Children's Hospital of San Diego

Opposition

California Grocers Association

HISTORY:

Date	Action
Apr. 25	From committee with author's amendments. Read second time and amended. Re-referred to Com. on PUB. S.
Apr. 21	Set for hearing May 3.
Mar. 17	Hearing postponed by committee.
Mar. 9	Set for hearing March 22.
Mar. 3	Referred to Com. on PUB. S.
Feb. 18	From printer. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MAY 10, 2011

AMENDED IN SENATE APRIL 25, 2011

SENATE BILL No. 514

Introduced by Senator Simitian

February 17, 2011

An act to add Sections 11110 and 11111 to the Health and Safety Code, relating to nonprescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 514, as amended, Simitian. Dextromethorphan: sale to minors prohibited.

Existing law prohibits a manufacturer, wholesaler, retailer, or other person from selling, transferring, or otherwise furnishing a specified substance, including ephedrine and pseudoephedrine, to a person under 18 years of age, except as specified. A first violation of this provision is a misdemeanor. Existing law further regulates the sale of nonprescription drugs, as specified.

This bill would, in addition, make it an infraction, *punishable by a fine not exceeding $250*, for any person, corporation, or retail distributer, in an over-the-counter sale to, without a prescription, to willfully and knowingly supply, deliver, or give possession of a nonprescription drug containing dextromethorphan to a person under 18 years of age. The bill would provide that proof that bona fide evidence of majority and identity was demanded and shown shall be a defense to any criminal prosecution.

The bill would further provide that a retail clerk who fails to require and obtain proof of age from the purchaser shall not be guilty of an infraction or subject to any civil penalties, unless the retail clerk is a willful participant in an ongoing criminal conspiracy to violate the

provisions prohibiting the sale of dextromethorphan to minors. By creating new crimes, this bill would impose a state-mandated local program.

The bill would require a person, corporation, or retail distributor that sells a product containing dextromethorphan to use a cash register that is equipped with an age-verification feature that directs the retail clerk to request identification before the product may be purchased, as provided.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11110 is added to the Health and Safety Code, to read:

11110. (a) It shall be an infraction, *punishable by a fine not exceeding two hundred fifty dollars ($250)*, for any person, corporation, or retail distributor to willfully and knowingly supply, deliver, or give possession of a drug, material, compound, mixture, preparation, or substance containing any quantity of dextromethorphan (the dextrorotatory isomer of 3-methoxy-N-methylmorphinan, including its salts, but not including its racemic or levorotatory forms) to a person under 18 years of age in an over-the-counter sale without a prescription.

(b) It shall be prima facie evidence of a violation of this section if the person, corporation, or retail distributor making the sale does not require and obtain bona fide evidence of majority and identity from the purchaser, unless from the purchaser's outward appearance the person making the sale would reasonably presume the purchaser to be 25 years of age or older.

(c) Proof that a person, corporation, or retail distributor, or his or her agent or employee, demanded, was shown, and acted in reasonable reliance upon, bona fide evidence of majority and identity shall be a defense to any criminal prosecution under this section. As used in this section, "bona fide evidence of majority

and identity" means a document issued by a federal, state, county, or municipal government, or subdivision or agency thereof, including, but not limited to, a motor vehicle operator's license, California state identification card, identification card issued to a member of the Armed Forces, or other form of identification that bears the name, date of birth, description, and picture of the person.

(d) (1) Notwithstanding any other provision of this section, a retail clerk who fails to require and obtain proof of age from the purchaser shall not be guilty of an infraction pursuant to subdivision (a) or subject to any civil penalties.

(2) This subdivision shall not apply to a retail clerk who is a willful participant in an ongoing criminal conspiracy to violate this section.

SEC. 2. Section 11111 is added to the Health and Safety Code, to read:

11111. A person, corporation, or retail distributor that sells or makes available products containing dextromethorphan, as defined in subdivision (a) of Section 11110, in an over-the-counter sale without a prescription shall, if feasible, use a cash register that is equipped with an age-verification feature to monitor age-restricted items. The cash register shall be programmed to direct the retail clerk making the sale to request bona fide evidence of majority and identity, as described in subdivision (c) of Section 11110, before a product containing dextromethorphan may be purchased.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN SENATE JULY 12, 2011

AMENDED IN SENATE JUNE 7, 2011

AMENDED IN SENATE JUNE 6, 2011

AMENDED IN ASSEMBLY MAY 4, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL No. 1424

Introduced by Assembly Member Perea

March 22, 2011

An act to amend Sections 31, 476, and 7145.5 of, and to add Section 494.5 to, the Business and Professions Code, to add Section ~~12419~~ *12419.13* to the Government Code, to add Section 10295.4 to the Public Contract Code, and to amend ~~Section~~ *Sections 7063 and* 19195 of, to add Sections *6834, 6835, 7057,* 19265, 19377.5, and 19571 to, *to add Article 9 (commencing with Section 6850) to Chapter 6 of Part 1 of Division 2 of,* and to add Article 7 (commencing with Section 19291) to Chapter 5 of Part 10.2 of Division 2 of, the Revenue and Taxation Code, relating to taxation.

LEGISLATIVE COUNSEL'S DIGEST

AB 1424, as amended, Perea. Franchise Tax Board: delinquent tax debt.

The Personal Income Tax Law and the Corporation Tax Law impose taxes on, or measured by, income. Existing law requires the Franchise Tax Board to make available as a matter of public record each calendar year a list of the 250 largest tax delinquencies in excess of $100,000, and requires the list to include specified information with respect to each delinquency. Existing law requires every board, as defined, and

the Department of Insurance, upon request of the Franchise Tax Board, to furnish to the Franchise Tax Board certain information with respect to every licensee.

This bill would require the *State Board of Equalization and the* Franchise Tax Board to *each* make available a list of the ~~250~~ *500* largest tax delinquencies described above at least twice each calendar year. This bill would require the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and licence number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. This bill would require a person whose delinquency appeared on ~~the~~ *either* list and whose name has been removed, as provided, to comply with the terms of the arranged resolution, and would authorize *the State Board of Equalization and* the Franchise Tax Board, if the person fails to comply with the terms of the arranged resolution, to add the person's name to the list without providing prior written notice, as provided.

This bill would permit a state governmental licensing entity, that issues professional or occupational licenses, certificates, registrations, or permits, to suspend, revoke, or refuse to issue a license if the licensee's name is included on ~~the~~ *either* list of the ~~250~~ *500* largest tax delinquencies described above. This bill would also require those licensing entities to provide to *the State Board of Equalization and* the Franchise Tax Board the name and social security number or federal taxpayer identification number of each individual licensee of that entity, and would require each application for a new license or renewal of a license to indicate on the application that the law allows *the State Board of Equalization and* the Franchise Tax Board to share taxpayer information with a board and requires the licensee to pay his or her state ~~income~~ tax obligation and that his or her license may be suspended if the state ~~income~~ tax obligation is not paid. The bill would require *the State Board of Equalization and* the Franchise Tax Board, if an individual licensee appears on ~~the~~ *either* list of the ~~250~~ *500* largest tax delinquencies described above, and the specified licensing entity has not made a decision regarding suspension or revocation of the license, to send a notice of suspension to the licensee. The bill would provide that the license of a licensee who fails to satisfy the unpaid taxes by a certain date shall be automatically suspended, except as specified, and

would require *the State Board of Equalization or* the Franchise Tax Board to mail a notice of suspension to the applicable state governmental licensing entity and to the licensee, and would provide that the suspension be canceled upon compliance with the tax obligation. The bill would require *the State Board of Equalization and* the Franchise Tax Board to meet certain requirements and would make related changes.

The bill would provide that the release or other use of information received by a state governmental licensing entity pursuant to these provisions, except as authorized, is punishable as a misdemeanor. By creating a new crime, the bill would impose a state-mandated local program.

This bill would also prohibit a state agency from entering into any contract for the acquisition of goods or services with a contractor whose name appears on ~~the~~ *either* list of the ~~250~~ *500* largest tax delinquencies described above.

Existing law authorizes the Franchise Tax Board to collect specified amounts for the Department of Industrial Relations and specified amounts imposed by a court pursuant to specified procedures.

This bill would authorize *the State Board of Equalization and* the Franchise Tax Board to enter into an agreement to collect any delinquent tax debt due to the Internal Revenue Service or any other state imposing an income tax or tax measured by income pursuant to specified procedures, provided that the Internal Revenue Service or that state has entered into an agreement to collect delinquent tax debts due to *the State Board of Equalization or* the Franchise Tax Board, and the agreements do not cause the net displacement of civil service employees, as specified. This bill would require the Controller, upon execution of a reciprocal agreement between *the State Board of Equalization,* the Franchise Tax Board, and any other state imposing *a sales and use tax, a tax similar to a sales and use tax,* an income tax, or tax measured by income, to offset any delinquent tax debt due to that other state from a person or entity, against any refund under the Personal Income Tax Law or the Corporation Tax Law owed to that person or entity, as provided.

This bill would incorporate additional changes to Section 7145.5 of the Business and Professions Code, proposed by AB 1307, to be operative as specified.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 31 of the Business and Professions Code is amended to read:

31. (a) As used in this section, "board" means any entity listed in Section 101, the entities referred to in Sections 1000 and 3600, the State Bar, the Department of Real Estate, and any other state agency that issues a license, certificate, or registration authorizing a person to engage in a business or profession.

(b) Each applicant for the issuance or renewal of a license, certificate, registration, or other means to engage in a business or profession regulated by a board who is not in compliance with a judgment or order for support shall be subject to Section 17520 of the Family Code.

(c) "Compliance with a judgment or order for support" has the meaning given in paragraph (4) of subdivision (a) of Section 17520 of the Family Code.

(d) Each licensee whose name appears on a list of the ~~250~~ *500* largest tax delinquencies pursuant to Section *7063 or* 19195 of the Revenue and Taxation Code shall be subject to Section 494.5 or 7145.5 or to Section *6834 or* 19265 of the Revenue and Taxation Code.

(e) Each application for a new license or renewal of a license shall indicate on the application that the law allows *the State Board of Equalization and* the Franchise Tax Board to share taxpayer information with a board and requires the licensee to pay his or her state ~~income~~ tax obligation and that his or her license may be suspended if the state ~~income~~ tax obligation is not paid.

(f) For purposes of this section, "tax obligation" means the tax imposed under, or in accordance with, Part 1 (commencing with Section 6001), Part 1.5 (commencing with Section 7200), Part 1.6 (commencing with Section 7251), Part 1.7 (commencing with

Section 7285), Part 10 (commencing with Section 17001), and Part 11 (commencing with Section 23001) of Division 2 of the Revenue and Taxation Code.

SEC. 2. Section 476 of the Business and Professions Code is amended to read:

476. (a) Except as provided in subdivision (b), nothing in this division shall apply to the licensure or registration of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3, or pursuant to Division 9 (commencing with Section 23000) or pursuant to Chapter 5 (commencing with Section 19800) of Division 8.

(b) Section 494.5 shall apply to the licensure of persons authorized to practice law pursuant to Chapter 4 (commencing with Section 6000) of Division 3, and the licensure or registration of persons pursuant to Chapter 5 (commencing with Section 19800) of Division 8 or pursuant to Division 9 (commencing with Section 23000).

SEC. 3. Section 494.5 is added to the Business and Professions Code, to read:

494.5. (a) A state governmental licensing entity may refuse to issue, reactivate, reinstate, or renew a license or may suspend a license if a licensee's name is included on a certified list.

(1) Until the liabilities covered by this section are satisfied, the qualifying person and any other personnel of record named on a license who have been suspended under this section shall be prohibited from serving in any capacity that is subject to licensure, but shall be permitted to act in the capacity of a nonsupervising bona fide employee.

(2) The license of any other renewable licensed entity with any of the same personnel of record who have been assessed an outstanding liability covered by this section shall be suspended until the liability has been satisfied or until the same personnel of record disassociate themselves from the renewable licensed entity.

(b) For purposes of this section:

(1) "Certified list" means ~~a~~ *either* list provided by the *State Board of Equalization or the* Franchise Tax Board of persons whose names appear on ~~a list~~ *the lists* of the ~~250~~ *500* largest tax delinquencies pursuant to Section *7063 or* 19195 of the Revenue and Taxation Code.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate, registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) (A) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California Highway Patrol.

(B) "State governmental licensing entity" shall not include any entity described in subparagraph (A) that has elected to decline to exercise the authority provided by this section to suspend or refuse to issue, reinstate, reactivate, or renew the license of a licensee for failure to pay the taxes described in subdivision (a). An election under this subparagraph shall not be valid unless notification of that election has been provided to *the State Board of Equalization and* the Franchise Tax Board at the time and in the manner prescribed by *the State Board of Equalization and* the Franchise Tax Board.

(c) The *State Board of Equalization and the* Franchise Tax Board shall ~~submit a~~ *each submit its respective* certified list to state governmental licensing entities.

(d) Notwithstanding any other law, all state governmental licensing entities shall collect the social security number or the federal taxpayer identification number from all applicants for the purposes of matching the names of the certified ~~list~~ *lists* provided by *the State Board of Equalization and* the Franchise Tax Board to applicants and licensees.

(e) (1) Each state governmental licensing entity shall determine whether an applicant or licensee is on the most recent certified list

provided by *the State Board of Equalization and* the Franchise Tax Board. The state governmental licensing entity shall have the authority to withhold issuance or renewal of the license of any applicant on ~~the~~ *either* list or to suspend the license of any licensee on ~~the~~ *either* list.

(2) If an applicant or licensee is on ~~a certified list~~ *either of the certified lists*, the state governmental licensing entity shall immediately provide a preliminary notice to the applicant or licensee of the entity's intent to suspend or withhold issuance or renewal of the license. The preliminary notice shall be delivered personally or by mail to the applicant's or licensee's last known mailing address on file with the state governmental licensing entity within 30 days of receipt of the certified list. Service by mail shall be completed in accordance with Section 1013 of the Code of Civil Procedure.

(A) The state governmental licensing entity shall issue a temporary license valid for a period of 90 days to any applicant whose name is on a certified list if the applicant is otherwise eligible for a license.

(B) The 90-day time period for a temporary license shall not be extended. Only one temporary license shall be issued during a regular license term and the term of the temporary license shall coincide with the first 90 days of the regular license term. A license for the full term or the remainder of the license term may be issued or renewed only upon compliance with this section.

(C) In the event that a license is suspended or an application for a license or the renewal of a license is denied pursuant to this section, any funds paid by the applicant or licensee shall not be refunded by the state governmental licensing entity.

(f) A state governmental licensing entity shall make a final determination to refuse to issue or to suspend a license pursuant to this section no sooner than 30 days and no later than 90 days of the mailing of the preliminary notice described in paragraph (2) of subdivision (e). The procedures in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the revocation or suspension of a license pursuant to this section.

(g) Notices shall be developed by each state governmental licensing entity. ~~The~~ *For an applicant or licensee on the State Board of Equalization's certified list, the notice shall include the address and telephone number of the State Board of Equalization, and shall emphasize the necessity of obtaining a release from the State Board of Equalization as a condition for the issuance, renewal, or continued valid status of a license or licenses. For an applicant or licensee on the Franchise Tax Board's certified list, the* notice shall include the address and telephone number of the Franchise Tax Board, and shall emphasize the necessity of obtaining a release from the Franchise Tax Board as a condition for the issuance, renewal, or continued valid status of a license or licenses.

(1) The notice shall inform the applicant that the state governmental licensing entity shall issue a temporary license, as provided in subparagraph (A) of paragraph (2) of subdivision (e), for 90 calendar days if the applicant is otherwise eligible and that upon expiration of that time period, the license will be denied unless the state governmental licensing entity has received a release from *the State Board of Equalization and* the Franchise Tax Board.

(2) The notice shall inform the licensee that any license suspended under this section will remain suspended unless the state governmental licensing entity receives a release along with applications and fees, if applicable, to reinstate the license.

(3) The notice shall also inform the applicant or licensee that if an application is denied or a license is suspended pursuant to this section, any moneys paid by the applicant or licensee shall not be refunded by the state governmental licensing entity. The state governmental licensing entity shall also develop a form that the applicant or licensee shall use to request a release by *the State Board of Equalization and* the Franchise Tax Board. A copy of this form shall be included with every notice sent pursuant to this subdivision.

(h) If the applicant or licensee wishes to challenge the submission of his or her name on a certified list, the applicant or licensee shall make a timely written request for release to *the State Board of Equalization or* the Franchise Tax ~~Board.~~ *Board, whichever is applicable.* The *State Board of Equalization or the* Franchise Tax Board shall immediately send a release to the

appropriate state governmental licensing entity and the applicant or licensee, if any of the following conditions are met:

(1) The applicant or licensee has complied with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section *6832 or* 19008 of the Revenue and Taxation Code, to satisfy the unpaid taxes.

(2) The applicant or licensee has submitted a request for release not later than 45 days after the applicant's or licensee's receipt of a preliminary notice described in paragraph (2) of subdivision (e), but *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* will be unable to complete the release review and send notice of its findings to the applicant or licensee and state governmental licensing entity within 45 days after *the State Board of Equalization's or* the Franchise Tax Board's receipt of the applicant's or licensee's request for release. Whenever a release is granted under this paragraph, and, notwithstanding that release, the applicable license or licenses have been suspended erroneously, the state governmental licensing entity shall reinstate the applicable licenses with retroactive effect back to the date of the erroneous suspension and that suspension shall not be reflected on any license record.

(3) The applicant or licensee *that is on the certified list provided by the Franchise Tax Board* is unable to pay the outstanding liability due to a current financial hardship, as determined by the Franchise Tax Board.

(i) An applicant or licensee is required to act with diligence in responding to notices from the state governmental licensing entity and *the State Board of Equalization or* the Franchise Tax Board with the recognition that the temporary license will lapse or the license suspension will go into effect after 90 days and that *the State Board of Equalization or* the Franchise Tax Board must have time to act within that period. An applicant's or licensee's delay in acting, without good cause, which directly results in the inability of *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* to complete a review of the applicant's or licensee's request for release shall not constitute the diligence required under this section which would justify the issuance of a release. An applicant or licensee shall have the burden of establishing that he or she diligently responded to notices from the

state governmental licensing entity or *the State Board of Equalization or* the Franchise Tax Board and that any delay was not without good cause.

(j) The *State Board of Equalization or the* Franchise Tax Board shall create release forms for use pursuant to this section. When the applicant or licensee has complied with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* shall mail a release form to the applicant or licensee and provide a release to the appropriate state governmental licensing entity. Any state governmental licensing entity that has received a release from *the State Board of Equalization and* the Franchise Tax Board pursuant to this subdivision shall process the release within five business days of its receipt. If *the State Board of Equalization or* the Franchise Tax Board determines subsequent to the issuance of a release that the licensee has not complied with their installment payment agreement, *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* may notify the state governmental licensing entity and the licensee in a format prescribed by *the State Board of Equalization and* the Franchise Tax Board that the licensee is not in compliance and the release shall be rescinded. The *State Board of Equalization and the* Franchise Tax Board may, when it is economically feasible for the state governmental licensing entity to develop an automated process for complying with this subdivision, notify the state governmental licensing entity in a manner prescribed by *the State Board of Equalization and* the Franchise Tax Board, that the licensee has not complied with the installment payment agreement. Upon receipt of this notice, the state governmental licensing entity shall immediately notify the licensee on a form prescribed by the state governmental licensing entity that the licensee's license will be suspended on a specific date, and this date shall be no longer than 30 days from the date the form is mailed. The licensee shall be further notified that the license will remain suspended until a new release is issued in accordance with subdivision (h).

(k) The *State Board of Equalization and the* Franchise Tax Board may enter into interagency agreements with the state governmental licensing entities necessary to implement this section, to the extent that it is cost effective to implement this section.

(*l*) Notwithstanding any other law, a state governmental licensing entity, with the approval of the appropriate department director or governing body, may impose a fee on a licensee whose license has been suspended pursuant to this section. The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(m) The process described in subdivision (h) shall constitute the sole administrative remedy for contesting the issuance of a temporary license or the denial or suspension of a license under this section. The procedures specified in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the denial, suspension, or failure to issue or renew a license or the issuance of a temporary license pursuant to this section.

(n) Any state governmental licensing entity receiving an inquiry as to the licensed status of an applicant or licensee who has had a license denied or suspended under this section or who has been granted a temporary license under this section shall respond only that the license was denied or suspended or the temporary license was issued pursuant to this section. Information collected pursuant to this section by any state agency, board, or department shall be subject to the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code).

(o) Any rules and regulations issued pursuant to this section by any state agency, board, or department may be adopted as emergency regulations in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety, or general welfare. The regulations shall become effective immediately upon filing with the Secretary of State.

(p) The *State Board of Equalization, the* Franchise Tax Board, and state governmental licensing entities, as appropriate, shall adopt regulations as necessary to implement this section.

(q) (1) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from *the State Board of Equalization or* the Franchise Tax Board, pursuant to this section, except to inform the public of the suspension of a license pursuant to this section. The release or other use of information received by a state governmental licensing entity pursuant to this section, except as authorized by this section, is punishable as a misdemeanor. This subdivision may not be interpreted to prevent the State Bar of California from filing a request with the Supreme Court of California to suspend a member of the bar pursuant to this section.

(2) To the extent permitted under federal law, a suspension or revocation of a license pursuant to this section shall not be reported to the National Practitioner Data Bank.

(r) If any provision of this section or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

(s) All rights to review afforded by this section to an applicant shall also be afforded to a licensee.

(t) (1) If the state governmental licensing entity, as defined in Section *6834 or* 19265 of the Revenue and Taxation Code, does not suspend, revoke, or deny renewal of a license within 90 days of the mailing of preliminary notice as described in subdivision (f), *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* is authorized to suspend the license pursuant to Section *6834 or* 19265 of the Revenue and Taxation Code.

(2) If the state governmental licensing entity has not suspended, revoked, or denied the renewal of a license within 90 days of the mailing of the preliminary notice as described in subdivision (e), the state governmental licensing entity shall promptly notify *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* and the licensee. The notification shall include the

reason why no action was taken by the state governmental licensing entity.

(3) If the election described in subparagraph (B) of paragraph (4) of subdivision (b) has been made, *the State Board of Equalization or* the Franchise Tax Board, *whichever is applicable,* is authorized to suspend, pursuant to Section *6834 or* 19265 of the Revenue and Taxation Code, the license of a licensee subject to the jurisdiction of the entity that made that election.

(u) Unless otherwise provided in this section, the policies, practices, and procedures of a state governmental licensing entity with respect to license suspensions under this section shall be the same as those applicable with respect to suspensions pursuant to Section 17520 of the Family Code.

(v) No provision of this section shall be interpreted to allow a court to review and prevent the collection of ~~income~~ taxes prior to the payment of those taxes in violation of the California Constitution.

(w) This section shall apply to any licensee whose name appears on ~~a list~~ *the lists* of the ~~250~~ *500* largest tax delinquencies pursuant to ~~Section~~ *Sections 7063 and* 19195 of the Revenue and Taxation Code on or after January 1, 2012.

SEC. 4. Section 7145.5 of the Business and Professions Code is amended to read:

7145.5. (a) The registrar may refuse to issue, reinstate, reactivate, or renew a license or may suspend a license for the failure of a licensee to resolve all outstanding final liabilities, which include taxes, additions to tax, penalties, interest, and any fees that may be assessed by the board, the Department of Industrial Relations, the Employment Development Department, or the Franchise Tax Board.

(1) Until the debts covered by this section are satisfied, the qualifying person and any other personnel of record named on a license that has been suspended under this section shall be prohibited from serving in any capacity that is subject to licensure under this chapter, but shall be permitted to act in the capacity of a nonsupervising bona fide employee.

(2) The license of any other renewable licensed entity with any of the same personnel of record that have been assessed an outstanding liability covered by this section shall be suspended

until the debt has been satisfied or until the same personnel of record disassociate themselves from the renewable licensed entity.

(b) The refusal to issue a license or the suspension of a license as provided by this section shall be applicable only if the registrar has mailed a notice preliminary to the refusal or suspension that indicates that the license will be refused or suspended by a date certain. This preliminary notice shall be mailed to the licensee at least 60 days before the date certain.

(c) In the case of outstanding final liabilities assessed by the Franchise Tax Board, this section shall be operative within 60 days after the Contractors' State License Board has provided the Franchise Tax Board with the information required under Section 30, relating to licensing information that includes the federal employee identification number or social security number.

(d) All versions of the application for contractors' licenses shall include, as part of the application, an authorization by the applicant, in the form and manner mutually agreeable to the Franchise Tax Board and the board, for the Franchise Tax Board to disclose the tax information that is required for the registrar to administer this section. The Franchise Tax Board may from time to time audit these authorizations.

(e) This section shall not be interpreted to conflict with the suspension of a license pursuant to Section 494.5 of this code or Section 19265 of the Revenue and Taxation Code.

SEC. 4.5. Section 7145.5 of the Business and Professions Code is amended to read:

7145.5. (a) The registrar may refuse to issue, reinstate, reactivate, or renew a license or may suspend a license for the failure of a licensee to resolve all outstanding final liabilities, which include taxes, additions to tax, penalties, interest, and any fees that may be assessed by the board, the Department of Industrial Relations, the Employment Development Department, ~~or~~ the Franchise Tax Board, *or the State Board of Equalization*.

(1) Until the debts covered by this section are satisfied, the qualifying person and any other personnel of record named on a license that has been suspended under this section shall be prohibited from serving in any capacity that is subject to licensure under this chapter, but shall be permitted to act in the capacity of a nonsupervising bona fide employee.

(2) The license of any other renewable licensed entity with any of the same personnel of record that have been assessed an outstanding liability covered by this section shall be suspended until the debt has been satisfied or until the same personnel of record disassociate themselves from the renewable licensed entity.

(b) The refusal to issue a license or the suspension of a license as provided by this section shall be applicable only if the registrar has mailed a notice preliminary to the refusal or suspension that indicates that the license will be refused or suspended by a date certain. This preliminary notice shall be mailed to the licensee at least 60 days before the date certain.

(c) In the case of outstanding final liabilities assessed by the Franchise Tax Board, this section shall be operative within 60 days after the Contractors' State License Board has provided the Franchise Tax Board with the information required under Section 30, relating to licensing information that includes the federal employee identification number or social security number.

(d) All versions of the application for contractors' licenses shall include, as part of the application, an authorization by the applicant, in the form and manner mutually agreeable to the Franchise Tax Board and the board, for the Franchise Tax Board to disclose the tax information that is required for the registrar to administer this section. The Franchise Tax Board may from time to time audit these authorizations.

(e) In the case of outstanding final liabilities assessed by the State Board of Equalization, this section shall not apply to any outstanding final liability if the licensee has entered into an installment payment agreement for that liability with the State Board of Equalization and is in compliance with the terms of that agreement.

(f) This section shall not be interpreted to conflict with the suspension of a license pursuant to Section 494.5 of this code or Section 6834 or 19265 of the Revenue and Taxation Code.

SEC. 5. Section 12419.13 is added to the Government Code, to read:

12419.13. (a) (1) The Controller shall, upon execution of a reciprocal agreement between *the State Board of Equalization or* the Franchise Tax Board, and any other state imposing *a sales and use tax,* an income tax, or tax measured by income, offset any delinquent tax debt due to that other state from a person or entity,

against any refund under *the Sales and Use Tax Law,* the Personal Income Tax Law, or the Corporation Tax Law owed to that person or entity.

(2) Standards and procedures for submission of requests for offsets shall be as prescribed by the Controller.

(3) Payment of the offset amount shall occur only after other offset requests for debts owed by a person or entity to this state or the federal government have been satisfied in accordance with the priority established under Section 12419.3.

(b) The reciprocal agreement identified in subdivision (a) shall prescribe the manner in which the administrative costs of the Controller, *the State Board of Equalization,* and the Franchise Tax Board shall be reimbursed.

SEC. 6. Section 10295.4 is added to the Public Contract Code, to read:

10295.4. (a) Notwithstanding any other law, a state agency shall not enter into any contract for the acquisition of goods or services with a contractor whose name appears on ~~the~~ *either* list of the ~~250~~ *500* largest tax delinquencies pursuant to Section *7063 or* 19195 of the Revenue and Taxation Code. Any contract entered into in violation of this subdivision is void and unenforceable.

(b) This section shall apply to any contract executed on or after January 1, 2012.

SEC. 7. Section 6834 is added to the Revenue and Taxation Code, to read:

6834. (a) (1) All state governmental licensing entities issuing professional or occupational licenses, certificates, registrations, or permits shall provide to the board the name and social security number or federal taxpayer identification number, as applicable, of each licensee of that state governmental licensing entity.

(2) If any licensee appears on a list of the 500 largest tax delinquencies pursuant to Section 7063, and the license of that licensee has not been suspended, revoked, or denied by the applicable state governmental licensing entity pursuant to Section 494.5 of the Business and Professions Code, then the board shall mail a preliminary notice of suspension to the licensee indicating that the license will be suspended by a date certain, which shall be at least 60 days after the mailing of the preliminary notice, unless prior to the date certain the licensee pays the unpaid taxes or enters into an installment payment agreement, as described in

Section 6832, to satisfy the unpaid taxes. The preliminary notice shall also advise the licensee of the opportunity to request deferral or cancellation of a suspension pursuant to subdivision (b).

(3) If any licensee subject to paragraph (2) fails to pay the unpaid taxes or to enter into an installment payment agreement, as described in Section 6832, to satisfy the unpaid taxes prior to the date certain listed in the preliminary notice of suspension, his or her license shall be automatically suspended by operation of this section, except as provided in subdivision (b), and the board shall provide a notice of suspension to the applicable state governmental licensing entity and shall mail a notice of suspension to the licensee. The rights, powers, and privileges of any licensee whose license to drive a motor vehicle, professional or occupational license, certificate, registration, or permit has been suspended pursuant to this section shall be subject to the same prohibitions, limitations, and restrictions as if the license to drive a motor vehicle, professional or occupational license, certificate, registration, or permit were suspended by the state governmental licensing entity that issued the professional or occupational license, certificate, registration, or permit.

(4) (A) Upon compliance by the licensee with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section 6832, to satisfy the unpaid taxes, a suspension pursuant to this subdivision shall be canceled. The board shall, within 10 business days of compliance by the licensee with the tax obligation, notify both the state governmental licensing entity and the licensee that the unpaid taxes have been paid or that an installment payment agreement, as described in Section 6832, has been entered into to satisfy the unpaid taxes and that the suspension has been canceled.

(B) Whenever a suspension is canceled under this paragraph and the applicable license or licenses have been suspended in error, the board shall notify the state governmental licensing entity to reinstate all applicable licenses back to the date of suspension and expunge any notation of that suspension from the licensee's record.

(5) If a license is not suspended, or if the suspension of a license is canceled, based on the licensee entering into an installment payment agreement as described in Section 6832, and the licensee fails to comply with the terms of the installment payment

agreement, that license shall be suspended as of the date that is 30 days after the date of termination of that installment payment agreement. If a license is suspended pursuant to this paragraph, the board shall provide notice of suspension to the applicable state governmental licensing entity and mail a notice of suspension to the licensee.

(6) State governmental licensing entities shall provide to the board the information required by this subdivision at a time that the board may require.

(b) (1) The board may defer or cancel any suspension authorized by this section if a licensee is unable to pay the liability due to a current financial hardship. The board shall, if requested by the licensee in writing, provide for an administrative hearing to determine if the licensee is unable to pay the liability due to a current financial hardship.

(2) The request for a hearing specified in paragraph (1) shall be made in writing within 30 days from the mailing date of the preliminary notice described in subdivision (a).

(3) The board shall conduct a hearing within 30 days after receipt of a request pursuant to paragraph (1), unless the board postpones the hearing, upon a showing of good cause by the licensee, in which case a suspension pursuant to subdivision (a) shall be deferred until the hearing has been completed.

(4) A licensee seeking relief under this subdivision shall only be entitled to relief described in paragraph (1) if the licensee provides the board with financial documents that substantiate a financial hardship, and agrees to an acceptable payment arrangement.

(5) If the deferral of a suspension of a license under this subdivision is no longer operative, that license shall be suspended as of the date that is 30 days after the date the deferral is no longer operative. If a license is suspended pursuant to this paragraph, the board shall provide notice of suspension to the applicable state governmental licensing entity and mail a notice of suspension to the licensee.

(c) For purposes of this section and Section 7057, the following definitions shall apply:

(1) "Financial hardship" means financial hardship, as determined by the board, where the licensee is financially unable to pay any part of the amount described in subdivision (a). In order

to establish the existence of a financial hardship, the licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the board for the purpose of making that determination.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate, registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420 of the Business and Professions Code, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California Highway Patrol. "State governmental licensing entity" shall not include the Department of Alcoholic Beverage Control or the State Bar of California.

(d) Notwithstanding any other law, a state governmental licensing entity may, with the approval of the appropriate department director or governing body, impose a fee on licensees whose license has been suspended as described in subdivision (a). The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(e) The process described in subdivision (b) shall constitute the sole administrative remedy for contesting the suspension of a license under this section. The procedures in the administrative adjudication provisions of the Administrative Procedure Act

(Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the suspension of a license pursuant to this section.

(f) This section shall apply to any licensee whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 on or after January 1, 2012.

SEC. 8. Section 6835 is added to the Revenue and Taxation Code, to read:

6835. (a) The board may enter into an agreement with the Internal Revenue Service or any other state imposing a sales and use tax, or a similar tax, for the purpose of collecting delinquent tax debts with respect to amounts assessed or imposed under this part, provided the agreements do not cause the net displacement of civil service employees. The agreement may provide, at the discretion of the board, the rate of payment and the manner in which compensation for services shall be paid.

(b) At the discretion of the board, the Internal Revenue Service or the other state collecting the tax debt pursuant to subdivision (a) may, as part of the collection process, refer the tax debt for litigation by its legal representatives in the name of the board.

(c) For purposes of this section, "displacement" includes layoff, demotion, involuntary transfer to a new class, involuntary transfer to a new location requiring a change of residence, and time base reductions. "Displacement" does not include changes in shifts or days off, nor does it include reassignment to any other position within the same class and general location.

SEC. 9. Article 9 (commencing with Section 6850) is added to Chapter 6 of Part 1 of Division 2 of the Revenue and Taxation Code, to read:

Article 9. Collection of Tax Debts Due to the Internal Revenue Services or Other States

6850. (a) The board may enter into an agreement to collect any delinquent tax debt due to the Internal Revenue Service or any other state imposing a sales and use tax, or similar tax, if, pursuant to Section 6851, the Internal Revenue Service or such a state has entered into an agreement to collect delinquent tax debts due to the board.

(b) Upon written notice to the debtor from the board, any amount referred to the board under subdivision (a) shall be treated as final and due and payable to the State of California, and shall be collected from the debtor by the board in any manner authorized under the law for collection of a delinquent sales and use tax liability, including, but not limited to, the recording of a notice of state tax lien under Article 2 (commencing with Section 7170) of Chapter 14 of Division 7 of Title 1 of the Government Code, and the issuance of an order and levy under Article 4 (commencing with Section 706.070) of Chapter 5 of Division 2 of Title 9 of Part 2 of the Code of Civil Procedure in the manner provided for earnings withholding orders for taxes.

(c) This part shall apply to amounts referred under this section in the same manner and with the same force and effect and to the full extent as if the language of those laws had been incorporated in full into this section, except to the extent that any provision is either inconsistent with this section or is not relevant to this section.

(d) The activities required to implement and administer this section shall not interfere with the primary mission of the board to administer this part.

(e) In no event shall a collection under this section be construed as a payment of sales and use taxes imposed under this part, or in accordance with Part 1.5 or Part 1.6.

SEC. 10. Section 7057 is added to the Revenue and Taxation Code, to read:

7057. (a) The board may disclose to state governmental licensing entities information regarding suspension of a license pursuant to Section 6834 of this code or Section 494.5 or 7145.5 of the Business and Professions Code.

(b) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from the board, pursuant to this section, except to inform the public of the suspension of a license pursuant to Section 6834 of this code or Section 494.5 or 7145.5 of the Business and Professions Code.

(c) For purposes of this section, the definitions in Section 6834 shall apply.

SEC. 11. Section 7063 of the Revenue and Taxation Code is amended to read:

7063. (a) Notwithstanding any other provision of law, the board shall make available as a matter of public record each quarter a list of the ~~250~~ *500* largest tax delinquencies in excess of one hundred thousand dollars ($100,000) under this part. For purposes of compiling the list, a tax delinquency means an amount owed to the board which is all of the following:

(1) Based on a determination made under Article 2 (commencing with Section 6481) or Article 3 (commencing with Section 6511) of Chapter 5 deemed final pursuant to Article 5 (commencing with Section 6561) of Chapter 5, or that is "due and payable" under Article 4 (commencing with Section 6536) of Chapter 5, or self-assessed by the taxpayer.

(2) Recorded as a notice of state tax lien pursuant to Chapter 14 (commencing with Section 7150) of Division 7 of Title 1 of the Government Code, in any county recorder's office in this state.

(3) For an amount of tax delinquent for more than 90 days.

(b) For purposes of the list, a tax delinquency does not include any of the following and may not be included on the list:

(1) A delinquency that is under litigation in a court of law.

(2) A delinquency for which payment arrangements have been agreed to by both the taxpayer and the board and the taxpayer is in compliance with the arrangement.

(3) A delinquency for which the taxpayer has filed for bankruptcy protection pursuant to Title 11 of the United States Code.

(c) Each quarterly list shall, with respect to each delinquency, include all the following:

(1) The name of the person or persons liable for payment of the tax and that person's or persons' last known address.

(2) The amount of tax delinquency as shown on the notice or notices of state tax lien and any applicable interest or penalties, less any amounts paid.

(3) The earliest date that a notice of state tax lien was filed.

(4) The type of tax that is delinquent.

(d) Prior to making a tax delinquency a matter of public record as required by this section, the board shall provide a preliminary written notice to the person or persons liable for the tax by certified mail, return receipt requested. If within 30 days after issuance of the notice, the person or persons do not remit the amount due or

make arrangements with the board for payment of the amount due, the tax delinquency shall be included on the list.

(e) The quarterly list described in subdivision (a) shall include the following:

(1) The telephone number and address of the board office to contact if a person believes placement of his or her name on the list is in error.

(2) The aggregate number of persons that have appeared on the list who have satisfied their delinquencies in their entirety and the dollar amounts, in the aggregate, that have been paid attributable to those delinquencies.

(f) As promptly as feasible, but no later than 5 business days from the occurrence of any of the following, the board shall remove that taxpayer's name from the list of tax delinquencies:

(1) Tax delinquencies for which the person liable for the tax has contacted the board and resolution of the delinquency has been arranged.

(2) Tax delinquencies for which the board has verified that an active bankruptcy proceeding has been initiated.

(3) Tax delinquencies for which the board has verified that a bankruptcy proceeding has been completed and there are no assets available with which to pay the delinquent amount or amounts.

(4) Tax delinquencies that the board has determined to be uncollectible.

(g) A person whose delinquency appears on the quarterly list, and who satisfies that delinquency in whole or in part, may request the board to include in its quarterly list any payments that person made to satisfy the delinquency. Upon receipt of that request, the board shall include those payments on the list as promptly as feasible.

(h) Notwithstanding subdivision (a), a person whose delinquency appeared on the quarterly list and whose name has been removed pursuant to paragraph (1) of subdivision (f) shall comply with the terms of the arranged resolution. If a person fails to do so, the board shall add that person's name to the list of delinquencies without providing the prior written notice required by subdivision (d).

~~SEC. 7.~~

SEC. 12. Section 19195 of the Revenue and Taxation Code is amended to read:

19195. (a) Notwithstanding any other provision of law, including Section 6254.21 of the Government Code, the Franchise Tax Board shall make available as a matter of public record at least twice each calendar year a list of the ~~250~~ *500* largest tax delinquencies in excess of one hundred thousand dollars ($100,000) under Part 10 and Part 11 of this division. For purposes of compiling the list, a tax delinquency means the total amount owed by a taxpayer to the State of California for which a notice of state tax lien has been recorded in any county recorder's office in this state, pursuant to Chapter 14 (commencing with Section 7150) of Division 7 of Title 1 of the Government Code.

(b) For purposes of the list, a tax delinquency does not include any of the following and may not be included on the list:

(1) A delinquency for which payment arrangements have been agreed to by both the taxpayer and the Franchise Tax Board and the taxpayer is in compliance with the arrangement.

(2) A delinquency for which the taxpayer has filed for bankruptcy protection pursuant to Title 11 of the United States Code.

(3) A delinquency for which the person or persons liable for the tax have contacted the Franchise Tax Board and for which resolution of the tax delinquency has been accepted by the Franchise Tax Board.

(c) Each list shall, with respect to each delinquency, include all the following:

(1) The name of the person or persons liable for payment of the tax and that person's or persons' address.

(2) The amount of tax delinquency as shown on the notice or notices of state tax lien and any applicable interest or penalties, less any amounts paid.

(3) The earliest date that a notice of state tax lien was filed.

(4) The type of tax that is delinquent.

(5) The type, status, and license number of any occupational or professional license held by the person or persons liable for payment of the tax.

(6) The names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation.

(d) Prior to making a tax delinquency a matter of public record as required by this section, the Franchise Tax Board shall provide

a preliminary written notice to the person or persons liable for the tax by certified mail, return receipt requested. If within 30 days after issuance of the notice, the person or persons do not remit the amount due or make arrangements with the Franchise Tax Board for payment of the amount due, the tax delinquency shall be included on the list.

(e) The list described in subdivision (a) shall include the following:

(1) The telephone number and address of the Franchise Tax Board office to contact if a person believes placement of his or her name on the list is in error.

(2) The aggregate number of persons that have appeared on the list who have satisfied their delinquencies in their entirety and the dollar amounts, in the aggregate, that have been paid attributable to those delinquencies.

(f) As promptly as feasible, but no later than five business days from the occurrence of any of the following, the Franchise Tax Board shall remove that taxpayer's name from the list of tax delinquencies:

(1) Tax delinquencies for which the person liable for the tax has contacted the Franchise Tax Board and resolution of the delinquency has been arranged.

(2) Tax delinquencies for which the Franchise Tax Board has verified that an active bankruptcy proceeding has been initiated.

(3) Tax delinquencies for which the Franchise Tax Board has verified that a bankruptcy proceeding has been completed and there are no assets available with which to pay the delinquent amount or amounts.

(4) Tax delinquencies that the Franchise Tax Board has determined to be uncollectible.

(g) A person whose delinquency appears on the list, and who satisfies that delinquency in whole or in part, may request the Franchise Tax Board to include in its list any payments that person made to satisfy the delinquency. Upon receipt of that request, the Franchise Tax Board shall include those payments on the list as promptly as feasible.

(h) Notwithstanding subdivision (a), a person whose delinquency appeared on the list and whose name has been removed pursuant to paragraph (1) of subdivision (f) shall comply with the terms of the arranged resolution. If the person fails to do so, the Franchise

Tax Board may add that person's name to the list of delinquencies without providing the prior written notice otherwise required by subdivision (d).

~~SEC. 8.~~

SEC. 13. Section 19265 is added to the Revenue and Taxation Code, to read:

19265. (a) (1) All state governmental licensing entities issuing professional or occupational licenses, certificates, registrations, or permits shall provide to the Franchise Tax Board the name and social security number or federal taxpayer identification number, as applicable, of each licensee of that state governmental licensing entity.

(2) If any licensee appears on a list of the ~~250~~ *500* largest tax delinquencies pursuant to Section 19195, and the license of that licensee has not been suspended, revoked, or denied by the applicable state governmental licensing entity pursuant to Section 494.5 of the Business and Professions Code, then the Franchise Tax Board shall mail a preliminary notice of suspension to the licensee indicating that the license will be suspended by a date certain, which shall be at least 60 days after the mailing of the preliminary notice, unless prior to the date certain the licensee pays the unpaid taxes or enters into an installment payment agreement, as described in Section 19008, to satisfy the unpaid taxes. The preliminary notice shall also advise the licensee of the opportunity to request deferral or cancellation of a suspension pursuant to subdivision (b).

(3) If any licensee subject to paragraph (2) fails to pay the unpaid taxes or to enter into an installment payment agreement, as described in Section 19008, to satisfy the unpaid taxes prior to the date certain listed in the preliminary notice of suspension, his or her license shall be automatically suspended by operation of this section, except as provided in subdivision (b), and the Franchise Tax Board shall provide a notice of suspension to the applicable state governmental licensing entity and shall mail a notice of suspension to the licensee. The rights, powers, and privileges of any licensee whose license to drive a motor vehicle, professional or occupational license, certificate, registration, or permit has been suspended pursuant to this section shall be subject to the same prohibitions, limitations, and restrictions as if the license to drive a motor vehicle, professional or occupational license, certificate,

registration, or permit were suspended by the state governmental licensing entity that issued the professional or occupational license, certificate, registration, or permit.

(4) (A) Upon compliance by the licensee with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section 19008, to satisfy the unpaid taxes, a suspension pursuant to this subdivision shall be canceled. The Franchise Tax Board shall, within 10 business days of compliance by the licensee with the tax obligation, notify both the state governmental licensing entity and the licensee that the unpaid taxes have been paid or that an installment payment agreement, as described in Section 19008, has been entered into to satisfy the unpaid taxes and that the suspension has been canceled.

(B) Whenever a suspension is canceled under this paragraph and the applicable license or licenses have been suspended in error, the Franchise Tax Board shall notify the state governmental licensing entity to reinstate all applicable licenses back to the date of suspension and expunge any notation of that suspension from the licensee's record.

(5) If a license is not suspended, or if the suspension of a license is canceled, based on the licensee entering into an installment payment agreement as described in Section 19008, and the licensee fails to comply with the terms of the installment payment agreement, that license shall be suspended as of the date that is 30 days after the date of termination of that installment payment agreement. If a license is suspended pursuant to this paragraph, the Franchise Tax Board shall provide notice of suspension to the applicable state governmental licensing entity and mail a notice of suspension to the licensee.

(6) State governmental licensing entities shall provide to the Franchise Tax Board the information required by this subdivision at a time that the Franchise Tax Board may require.

(b) (1) The Franchise Tax Board may defer or cancel any suspension authorized by this section if a licensee is unable to pay the liability due to a current financial hardship. The Franchise Tax Board shall, if requested by the licensee in writing, provide for an administrative hearing to determine if the licensee is unable to pay the liability due to a current financial hardship.

(2) The request for a hearing specified in paragraph (1) shall be made in writing within 30 days from the mailing date of the preliminary notice described in subdivision (a).

(3) The Franchise Tax Board shall conduct a hearing within 30 days after receipt of a request pursuant to paragraph (1), unless the board postpones the hearing, upon a showing of good cause by the licensee, in which case a suspension pursuant to subdivision (a) shall be deferred until the hearing has been completed.

(4) A licensee seeking relief under this subdivision shall only be entitled to relief described in paragraph (1) if the licensee provides the Franchise Tax Board with financial documents that substantiate a financial hardship, and agrees to an acceptable payment arrangement.

(5) If the deferral of a suspension of a license under this subdivision is no longer operative, that license shall be suspended as of the date that is 30 days after the date the deferral is no longer operative. If a license is suspended pursuant to this paragraph, the Franchise Tax Board shall provide notice of suspension to the applicable state governmental licensing entity and mail a notice of suspension to the licensee.

(c) For purposes of this section and Section 19571, the following definitions shall apply:

(1) "Financial hardship" means financial hardship within the meaning of Section 19008, as determined by the Franchise Tax Board, where the licensee is financially unable to pay any part of the amount described in subdivision (a) and the licensee is unable to qualify for an installment payment arrangement as provided for by Section 19008. In order to establish the existence of a financial hardship, the licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the Franchise Tax Board for the purpose of making that determination.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate,

registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420 of the Business and Professions Code, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California Highway Patrol. "State governmental licensing entity" shall not include the Department of Alcoholic Beverage Control or the State Bar of California.

(d) Notwithstanding any other law, a state governmental licensing entity may, with the approval of the appropriate department director or governing body, impose a fee on licensees whose license has been suspended as described in subdivision (a). The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(e) The process described in subdivision (b) shall constitute the sole administrative remedy for contesting the suspension of a license under this section. The procedures in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the suspension of a license pursuant to this section.

(f) This section shall apply to any licensee whose name appears on a list of the ~~250~~ *500* largest tax delinquencies pursuant to Section 19195 on or after January 1, 2012.

~~SEC. 9.~~

SEC. 14. Article 7 (commencing with Section 19291) is added to Chapter 5 of Part 10.2 of Division 2 of the Revenue and Taxation Code, to read:

Article 7. Collection of Tax Debts Due to the Internal Revenue Service or Other States

19291. (a) The Franchise Tax Board may enter into an agreement to collect any delinquent tax debt due to the Internal Revenue Service or any other state imposing an income tax or tax measured by income if, pursuant to Section 19377.5, the Internal Revenue Service or that state has entered into an agreement to collect delinquent tax debts due the Franchise Tax Board.

(b) Upon written notice to the debtor from the Franchise Tax Board, any amount referred to the Franchise Tax Board under subdivision (a) shall be treated as final and due and payable to the State of California, and shall be collected from the debtor by the Franchise Tax Board in any manner authorized under the law for collection of a delinquent income tax liability, including, but not limited to, the recording of a notice of state tax lien under Article 2 (commencing with Section 7170) of Chapter 14 of Division 7 of Title 1 of the Government Code, and the issuance of an order and levy under Article 4 (commencing with Section 706.070) of Chapter 5 of Division 2 of Title 9 of Part 2 of the Code of Civil Procedure in the manner provided for earnings withholding orders for taxes.

(c) Part 10 (commencing with Section 17001), this part, Part 10.7 (commencing with Section 21001), and Part 11 (commencing with Section 23001) shall apply to amounts referred under this section in the same manner and with the same force and effect and to the full extent as if the language of those laws had been incorporated in full into this section, except to the extent that any provision is either inconsistent with this section or is not relevant to this section.

(d) The activities required to implement and administer this section shall not interfere with the primary mission of the Franchise Tax Board to administer Part 10 (commencing with Section 17001) and Part 11 (commencing with Section 23001).

(e) In no event shall a collection under this section be construed as a payment of income taxes imposed under Part 10 (commencing with Section 17001) or Part 11 (commencing with Section 23001).

~~SEC. 10.~~

SEC. 15. Section 19377.5 is added to the Revenue and Taxation Code, to read:

19377.5. (a) The Franchise Tax Board may enter into an agreement with the Internal Revenue Service or any other state imposing an income tax or tax measured by income for the purpose of collecting delinquent tax debts with respect to amounts assessed or imposed under Part 10 (commencing with Section 17001), this part, or Part 11 (commencing with Section 23001), provided the agreements do not cause the net displacement of civil service employees. The agreement may provide, at the discretion of the Franchise Tax Board, the rate of payment and the manner in which compensation for services shall be paid.

(b) At the discretion of the Franchise Tax Board, the Internal Revenue Service or the other state collecting the tax debt pursuant to subdivision (a) may, as part of the collection process, refer the tax debt for litigation by its legal representatives in the name of the Franchise Tax Board.

(c) For purposes of this section, "displacement" includes layoff, demotion, involuntary transfer to a new class, involuntary transfer to a new location requiring a change of residence, and time base reductions. "Displacement" does not include changes in shifts or days off, nor does it include reassignment to any other position within the same class and general location.

~~SEC. 11.~~

SEC. 16. Section 19571 is added to the Revenue and Taxation Code, to read:

19571. (a) The Franchise Tax Board may disclose to state governmental licensing entities information regarding suspension of a license pursuant to Section 19265 of this code or Sections 494.5 or 7145.5 of the Business and Professions Code.

(b) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from the Franchise Tax Board, pursuant to this section, except to inform the public of the suspension of a license pursuant to Section 19265 of this code or Sections 494.5 or 7145.5 of the Business and Professions Code.

(c) For purposes of this section, the definitions in Section 19265 shall apply.

SEC. 17. Section 4.5 of this bill incorporates amendments to Section 7145.5 of the Business and Professions Code proposed by both this bill and A.B. 1307. It shall only become operative if (1)

both bills are enacted and become effective on or before January 1, 2012, (2) each bill amends Section 7145.5 of the Business and Professions Code, and (3) this bill is enacted after A.B. 1307, in which case Section 4 of this bill shall not become operative.

~~SEC. 12.~~

SEC. 18. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because a local agency or school district has the authority to levy service charges, fees, or assessments sufficient to pay for the program or level of service mandated by this act or because costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1424 **VERSION: As Amended July 12, 2011**

AUTHOR: Perea **SPONSOR:**

SUBJECT: Collection of Delinquent Tax Debt

Affected Sections:

Business and Professions Code (B&PC): Amend §§ 31, 476 and 7145.5; Add §494.5
Government Code: Add §12419.13
Public Contract Code: Add §10295.4
Revenue and Taxation Code: Amend §§ 7063 and 19195; Add §§ 6834, 6835, 7057, 19265, 19377.5, 19571, Article 9 (commencing with §6850), and Article 7 (commencing with § 19291)

CURRENT STATUS: Senate Appropriations Hearing scheduled for August 15, 2011.

OVERVIEW

This bill amends and adds a variety of provisions to the Revenue and Taxation Code, the Public Contract and Government Codes, as well as the Business and Professions Code to provide for the collection of unpaid tax debt.

In its current form, the board would be required to compare its licensee data with the certified list of "500 largest tax delinquencies" prepared by the Franchise Tax Board and the Board of Equalization. If an applicant is on that list, and is otherwise able to be licensed, the board could issue only a temporary license for 150 days and further deny the application if the person does not satisfy the tax obligation or otherwise enter into an agreement with the FTB or BOE to satisfy the debt. For an existing licensee, the board would be required to issue a temporary license for 150 days. The bill requires the board to provide notice to an applicant or licensee of the provisions; requires the board to include specified statements on its license and renewal applications; create forms; and ensure it does not contract with a person or entity on the "Top 500" list.

EXISTING LAW, as it relates to the Board:

1. Federal law mandates the Financial Institution Data Match (FIDM) for the collection of delinquent child support payments. The California Franchise Tax Board (FTB) is responsible for collecting child support debts in California. The Department of Consumer Affairs (DCA) Family Support Unit receives information on delinquent child support orders. Licensees found to be noncompliant with a child support order are issued a temporary license – this action is used as tool to bring a licensee into compliance with a child support order. A licensee who then

does not come into compliance with a child support order is subject to additional actions against their license.

AS AMENDED THIS BILL WOULD:

1. Amend B&PC §31 to specify that each licensee whose name appears on a list of the 500 largest tax delinquencies (as certified by the BOE and FTB) is subject to temporary suspension of their license until a tax obligation is satisfied or until the licensee enters into an agreement with the FTB or BOE to pay the obligation, as specified. This section further requires the board to include a statement on its initial and renewal applications regarding the BOE's and FTB's right to share taxpayer information, that the licensee is required to pay his or her tax obligation, and that his or her license may be suspended if the state tax obligation is not paid.

2. Add B&PC § 494.5 to do the following, effective January 1, 2012:
   - Add definitions (Certified list, license, licensee, state governmental licensing entity).
   - Provide an "opt-out" provision for a state governmental licensing entity and, upon election, requirements to notify the BOE and FTB in a manner specified by those agencies.
   - Require the BOE and FTB to provide the board with certified lists of the 500 largest tax delinquencies.
   - Require the board to collect SSN or FEIN numbers from all applicants, for the purpose of matching names against the BOE / FTB certified lists.
   - Authorize the board to withhold issuance or renewal of a license for an applicant on the BOE / FTB lists.
   - Require the board to provide notice to applicants or licensees on the "Top 500" list, to be sent via certified mail, and the content of those notices.
   - Require the board to create forms, notices, and include specific statements on its license and renewal applications.
   - Specify that the Administrative Procedure Act shall not apply to the denial, suspension or failure to issue or renew a license as specified in this section; and specify that information collected by the board pursuant to this section is subject to the Information Practices Act.
   - Authorize a state agency to assess a fee to cover its costs related to these provisions, and to enter into Interagency Agreements with the BOE and FTB.
   - Authorize the board to adopt emergency regulations for the purpose of adopting rules and regulations related to this section. Also, require the BOE and FTB to adopt regulations necessary to implement this section.
   - Specify that a suspension or revocation of a license under this section shall not be reported to the National Practitioner Data Bank.
   - Require the board to notify the BOE or FTB it has <u>not</u> suspended, revoked or denied a license following 90 days of mailing a preliminary notice; authorize

the BOE or FTB to suspend a license if the licensing entity has not done so or "opts out."

- Specify that policies, practices and procedures used by the board shall be the same as those used by the licensing entity for the purpose of delinquent child support orders.
- Require a licensing entity, as specified, to provide the FTB with the name, SSN, FEIN of each licensee.
- Provide for the automatic suspension of a license if a person fails to pay unpaid taxes or fails to enter into an install payment agreement, as specified.
- Provide administrative remedies for the contesting of a suspension of a license; the process by which a suspension can be cancelled, as specified; provide definitions; and require the licensing entity to provide information to the FTB as required.

AUTHOR'S INTENT:
Staff has requested a Fact Sheet from the author's office.

FISCAL IMPACT:
Board staff anticipates that the measure as amended July 12, 2011, would require a half-time AGPA to implement the provisions of the bill.

SUPPORT/OPPOSITION:
According to the Senate Committee Analysis (for the June 7, 2011 version):
Support
California Tax Reform Association; Western Center on Law and Poverty

Opposition
California Association of Realtors
California Chapter of the American Fence Association
California Fence Contractors Association
Engineering Contractors Association
California Landscape Contractors Association
Marin Builders Association
Flasher Barricade Association

HISTORY:

Date	**Action**
2011	
July 12	Read second time and amended. Re-referred to Com. on APPR.
July 11	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 6. Noes 3.) (July 6).
June 22	In committee: Hearing postponed by committee.
June 7	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on

	GOV. & F.	
June 6	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on GOV. & F.	***[gut & amend]***
June 2	Referred to Com. on GOV. & F.	
May 26	In Senate. Read first time. To Com. on RLS. for assignment.	
May 26	Read third time. Passed. Ordered to the Senate. (Ayes 75. Noes 0. Page 1566.)	
May 19	Read second time. Ordered to consent calendar.	
May 18	From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 18).	
May 5	Re-referred to Com. on APPR.	
May 4	Read second time and amended.	
May 3	From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 9. Noes 0.) (May 2).	
May 2	In committee: Set, first hearing. Referred to REV. & TAX. suspense file.	
Mar. 31	Referred to Com. on REV. & TAX.	
Mar. 23	From printer. May be heard in committee April 22.	
Mar. 22	Read first time. To print.	

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	1. Secure extension of board's sunset date. *1st Qtr 06/07:* *Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.* *4th Qtr 06/07:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process.* *1st Qtr 08/09:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process.* *Board staff attend a stakeholders meeting with committee staff to discuss amendments.* *Governor signs SB 963 (Chapter 385, Statutes of 2008)* *1st Qtr 09/10:* *Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.* *2nd Qtr 09/10:* *Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.* *3rd Qtr 09/10:* *Sunset bills introduced* *AB 1659 (Huber) – State Government, Agency Repeals* *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection* *SB 954 (Harmon) – Legislative Procedure, Committee Referrals* *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations* *4th Qtr 09/10:* *SB 954 (Harmon) – Bill is dead (Failed deadline)* *SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)* *1st Qtr 10/11:* *Governor signs AB 1659 (Chapter 666, Statutes of 2010)* *Governor signs AB 2130 (Chapter 670, Statutes of 2010)*

2. Sponsor legislation to update pharmacy law.

Enacted - 1st Qtr. 08/09: *SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions*

Oct. 2007: *Board sponsors omnibus provisions for 2008. Four types of changes are discussed.*

(1) Changes specific to the PIC and DRC requirements

- *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*
- *Section 4036.5 – Pharmacist-in-Charge*
- *Section 4161 – Nonresident wholesaler*
- *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*
- *Section 4329 – Nonpharmacists; Prohibited Acts*
- *Section 4330 – Proprietors; Prohibited Acts*

(2) Changes to allow for the use of mobile pharmacies

- *Section 4062 – Furnishing Dangerous Drugs During an Emergency.*
- *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.*

(3) General changes

- *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.*
- *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*
- *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*
- *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*
- *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.*

(4) Changes based on recodification of Business and Professions Code section 4052

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

	Jan. 2008:	*Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.* *Board approved language for omnibus bill.*
	April 2008:	*Some provisions of omnibus bill removed:* • *Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.*
	Oct. 2008:	*Governor vetoes SB 1779*
	1st Qtr 08/09:	*Board seeks to pursue omnibus provisions (formerly contained in SB 1779).* *Four areas of change: (Included in SB 819)* *(1) Changes specific to the PIC and DRC requirements* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *(2) Changes to allow for the use of mobile pharmacies* • *Section 4062 – Furnishing Dangerous Drugs During an Emergency.* • *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.* *(3) General changes* • *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.* • *Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory* • *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.* • *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.* *H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.*

	(4) *Changes based on recodification of Business and Professions Code section 4052* • *Section 733 – Dispensing Prescription Drugs and Devices* • *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities* • *Section 4040 – Prescription; Content Requirements* • *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist* • *Section 4060 – Controlled Substance – Prescription Required, Exceptions* • *Section 4076 – Prescription Container – Requirements for Labeling* • *Section 4111 – Restrictions on Prescriber Ownership* • *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner* • *H&SC 11150 – Persons Authorized to Write or Issue a Prescription* ***1st Qtr 08/09:*** *Board seeks to introduce additional changes: (Included in SB 821)* • *Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4362 – Entry Into Pharmacists Recovery Program.* *New Provisions* • *4200.1 – Pharmacist Examination; Remedial Education* • *4112 – Non-resident Pharmacy: Registration Required* • *4146 – Return and Disposal of Sharps* • *4013 – Subscriber Alert* ***3rd Qtr 08/09:*** *SB 821 introduced*

2nd Qtr 09/10: *Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.*

3rd Qtr 09/10: *Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.*

Omnibus Proposal #1:

(1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)

- *§4017 – Authorized Officers of the Law*
- *§4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *§4028 – Definition of Licensed Hospital*
- *§4037 – Definition of Pharmacy*
- *§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations*
- *§4072 – Oral or Electronic Transmission of Prescription – Health Care Facility*
- *§4101 – Pharmacist-in-Charge, Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board Prescription: Exceptions.*
- *§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies*
- *§4127.1 – License to Compound Injectable Sterile Drug Products Required*
- *§4169 – Prohibited Acts (also, strike operative date of 2008)*
- *§4181 – License Requirements; Policies and Procedures; Who May Dispense*
- *§4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs*

(2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)

- *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions*

(3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)

- *§4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring*
- *§4426 – Department of Health Care Services to Study Reimbursement Rates*

Omnibus Proposal #2

(1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative-in-Charge

(2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)

(3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: *SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.*

4th Qtr 09/10: *Board establishes support position of SB 1489.*
SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies.
SB 1489 is amended to modify §4076.5 – Patient-Centered Prescription Labels to authorize the board to exempt long-term health care facilities from regulations.

1st Qtr 10/11: *Governor signs SB 1489 (Chapter 653, Statutes of 2010).*

2nd Qtr 10/11: *Board seeks to pursue omnibus provisions*
Section 4200 – Remove obsolete reference to prior pharmacist examination
Staff provides language to Senate Committee on Business, Professions and Economic Development for inclusion in an omnibus bill.

3rd Qtr 10/11: *Staff provides language to Senate Business Professions and Economic Development for inclusion in Omnibus Bill.*
SB 943 is introduced. Contains amendments to section 4200.

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sep. 30, 2006: *Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.*

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: *Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

Aug. 2008: *Regulatory effort initiated. (See Objective 3.2, Task 12)*

Oct. 2009: *Board approves regulatory language for Initial Notice.*

Jan. 2010: *Office of Administrative Law approves regulation.*

July 2010: *Regulation effective.*

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sep. 2006: *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*

Sep. 2008: *Governor signs SB 1307 which delays implementation of e-pedigree.*

	6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction. *Oct. 2007:* *Governor signs the following:* *AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.* *SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.* *SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.* *Governor vetoes the following:* *AB 249 (Eng) Healing Arts: Settlement Agreements.* *AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.* *AB 1025 (Bass) Professions and Vocations: Denial of Licensure.* *SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.* *Oct. 2008:* *Governor signs the following:* *AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks* *SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review* *Governor vetoes the following:* *AB 501 (Swanson) Pharmaceutical Devices* *AB 865 (Davis) State Agencies* *AB1574 (Plescia) Surgical Clinics: Licensure* *Jan. 2009:* *Legislation introduced affecting Pharmacy law:* *(New Session)* *AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections.* *SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.*

	4th Qtr 08/09:	*AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements* *AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License* *AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012* *AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid* *AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice* *AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container* *AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)* *AB 1370 (Solorio) "Best Before" Date on a Prescription Label* *AB 1458 (Davis) Drugs: Adverse Effects Reporting* *SB 26 (Simitian) Home-Generated Pharmaceutical Waste* *SB 43 (Alquist) Cultural and Linguistic Competency* *SB 238 (Calderon) Medical Information* *SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs* *SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus* *SB 484 (Wright) Ephedrine Products to Schedule V* *SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews* *SB 762 (Aanestad) Professions and Vocations; Healing Arts* *AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012* *AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid* *AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container* *AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)* *SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus* *SB 484 (Wright) Ephedrine Products to Schedule V* *SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews* *SB 762 (Aanestad) Professions and Vocations; Healing Arts*
	1st Qtr 09/10:	*Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts*
	2nd Qtr 09/10:	*Governor signs SB 819 (Omnibus)* *Governor vetoes SB 820 (Omnibus)* *Governor signs SB 821 (Omnibus)* *Governor signs SB 470 (Corbett) - "Purpose"* *Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset* *Governor signs AB 931 (Fletcher) - Emergency Supplies Container* *Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia*

	3rd Qtr 09/10: *Board considers new legislation* 1. *Board of Pharmacy* • *AB 2104 (Hayashi) – California State Board of Pharmacy* • *SB 1390 (Corbett) – Prescription Container Labels* 2. *Pharmacy Practice* • *AB 1869 (Anderson) – Pharmacy (spot bill)* • *AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors* 3. *Sunset Review and Legislative Oversight Proposals* • *AB 1659 (Huber) – State Government, Agency Repeals* • *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection* • *SB 954 (Harmon) – Legislative Procedure, Committee Referrals* • *SB 1171 (Negrete McLeod) – Regulatory Boards, Operations* • *SB 1172 (Negrete McLeod) – Sunset of Diversion Program* 4. *Regulation of Dangerous Drugs and Devices* • *AB 1455 (Hill) -- Pseudoephredrine* • *AB 2548 (Block) – CURES – Prescription Drug Monitoring Program* • *SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products* • *SB 1071 (DeSaulnier) – CURES* • *SB 1106 (Yee) – Prescribers – Dispensing of Samples* 5. *Pharmacy Licensing Issues* • *AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies* • *AB 2292 (Lowenthal) – Pharmacy: Clinics* • *AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program* 6. *Distribution of Needles and Syringes* • *AB 1701 (Chesbro) – Hypodermic Needles and Syringes* • *AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services* • *AB 2139 (Chesbro) – Solid Waste: Product Stewardship* • *SB 1029 (Yee) -- Hypodermic Needles and Syringes* 7. *General / Other* • *AB 2112 (Monning) – Prescription Record Privacy Act*

	4th Qtr 09/10:	*Board considers additional legislation* *AB 1939 (Fletcher) Sharps Waste* *SB1111 (Negrete McLeod) DCA Enforcement Model*
	Apr. 2010:	*Board takes positions on legislative measures:* *AB 1701 (Chesbro) Support* *AB 2104 (Hayashi) Oppose* *AB 2292 (Lowenthal) Support* *SB 1106 (Yee) Support if Amended* *AB 1916 (Davis) Bill is dead (failed deadline)* *AB 2112 (Monning) Bill is dead (failed deadline)* *SB 1111 (Negrete McLeod) Bill is dead (failed deadline)*
	May 2010:	*AB 1869 (Anderson) Bill is dead (failed deadline)* *AB 1939 (Fletcher) Bill is dead (failed deadline)*
	June 2010:	*SB 1390 (Corbett) Fails passage in policy committee* *SB 954 (Harman) Bill is dead (failed deadline)* *SB 1171 (Negrete McLeod) Bill is dead (failed deadline)* *AB 2139 (Chesbro) Bill is dead (failed deadline)* *AB 2292 (Lowenthal) Bill is dead (failed deadline)* *AB 2548 (Block) Bill is dead (Failed deadline)*
	Apr./May 2010:	*AB 2104 (Hayashi) Amended twice*
	June 2010:	*AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.*
	July 2010:	*AB 2077 (Solorio – Centralized Hospital Packaging Pharmacies. Board establishes Support position.*

	1st Qtr 10/11:	*Governor signs the following legislation:* *AB 2104 (Hayashi) – Requires DCA Director approval of the Board's appointment of Executive Officer (Chapter 374, Statutes of 2010)* *AB 1659 (Huber) – State Government, Agency Repeals (Chapter 666, Statutes of 2010)* *AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection (Chapter 670, Statutes of 2010)* *SB 1172 (Negrete McLeod) – Diversion Programs (Chapter 517, Statutes of 2010)* *AB 1071 (Chesbro) – Hypodermic Needles and Syringes (Chapter 667, Statutes of 2010)* *SB 1414 (Hill) – Apomorphine: Unscheduled (Chapter 76, Statutes of 2010)* *AB 2699 (Bass) – Licensure Exemption: State of Emergency (Chapter 270, Statutes of 2010)* *Governor vetoes the following legislation:* *AB 1858 (Blumenfield) – Hypodermic Needles and Syringes* *SB 1029 (Yee) – Hypodermic Needles and Syringes* *AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies* *SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products* *AB 2747 (Lowenthal) – Prisons: Pharmacy Services* *The following legislation fails passage:* *AB 1455 (Hill) – Pseudoephedrine* *SB 1071 (DeSaulnier) – CURES* *SB 1106 (Yee) – Prescribers Dispensing of Samples* *AB 2551 (Hernandez) – Pharmacy Technician Scholarship & Loan Repayment Program* *AB 1310 (Hernandez) – Healing Arts Database*
	2nd Qtr 10/11:	*SB 41 (Yee) Introduced – Hypodermic Needles and Syringes* *AB 36 (Hill) Introduced – Ephedrine: Retail Sale* *Board approves provisions for sponsorship in 2011/2012 Session:* *(1) Pharmacists Recovery Program* • *Section 4362 – Amend to require that a participant in the pharmacists recovery program be responsible to pay an administrative co-pay each month to cover a portion of the administrative costs borne by the board; provision to allow the board to waive or defer the requirement based on a demonstrated financial hardship.*

	3rd Qtr 10/11: *Board advised changes to 4362 will not be sought this year.* 1. *Board-Sponsored Legislation* *SB 431 (Emmerson) Pharmacies: regulation* • *Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors* • *Sections 4104, 4105 and 4112 – Enforcement Enhancements* 2. *Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction* a. *Board of Pharmacy/Licensing* • *AB 377 (Solorio) Pharmacy: Centralized hospital packaging* • *AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies* • *AB 847 (Lowenthal, Bonnie) Pharmacy: clinics* • *SB 100 (Price) Healing arts* • *SB 632 (Emmerson) Pharmacy* b. *Controlled Substances/Marijuana* • *AB 507 (Hayashi) Pain management* • *SB 847 (Correa) Medical Cannabis Licensing Act* • *SB 786 (Dutton) Controlled substances* c. *Reporting Requirements/Records* • *SB 260 (Cannella) Controlled substances* • *SB 315 (Wright) Ephedrine and pseudeophedrine* • *SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System* d. *Healing Arts/DCA* • *AB 675 (Hagman) Continuing education* • *AB 958 (Berryhill) Regulatory boards: limitation periods* • *AB 1003 (Smyth) Professional and vocational licenses* • *AB 1328 (Pan) Professions and vocations* • *SB 231 (Emmerson) Regulatory boards: healing arts* • *SB 227 (Wyland) Business and professions: licensure (corrected)* • *SB 538 (Price) Healing arts* • *SB 544 (Price) Healing arts* • *SB 667 (Wyland) Healing arts* e. *Other* • *AB 389 (Mitchell) Bleeding disorders: blood clotting products* • *AB 604 (Skinner) Needle exchange progams* • *SB 41 (Yee) Hypodermic Needles and Syringes* • *SB 514 (Simitian) Dextromethorphan: sale to minors prohibited* • *SB 850 (Leno) Medical records: confidential information*

	4th Qtr 10/11: *Board considers and establishes positions on the following legislation* *a. Board of Pharmacy/Licensing* • *AB 377 (Solorio) Pharmacy: Centralized hospital packaging - Support if amended* • *AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies -Support* *b. Controlled Substances/Marijuana* • *AB 507 (Hayashi) Pain management - Oppose* *c. Reporting Requirements/Records* • *SB 315 (Wright) Ephedrine and pseudeophedrine - Support* • *SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System - Watch* • *AB 1280 (Hill) Ephedrine Sales - Watch* *d. Healing Arts/DCA* • *SB 541 (Price) Extromethorphan: sale to minors prohibited - Support* *e. Other* • *AB 389 (Mitchell) Bleeding disorders: blood clotting products - Watch* • *AB 604 (Skinner) Needle exchange progams - Support* • *SB 41 (Yee) Hypodermic Needles and Syringes - Support if amended* • *SB 514 (Simitian) Dextromethorphan: sale to minors prohibited - Support*

	7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol. *March 2007:* *Licensing Committee considers and approves concept. More work is required.* *June 2007:* *Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.* *Sept. 2007:* *Licensing Committee forwards to full board legislative proposal.* *Oct. 2007:* *Board approved draft legislation.* *Nov. 2007:* *Staff meeting with stakeholders to elicit support for the proposal.* *Dec. 2007:* *Staff develop fact sheets and work with experts in immunizations.* *Feb. 2009:* *Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.* *April 2009:* *Bill amended to allow pharmacists to initiate and administer pneumonoccocal and influenza vaccines.* *May 2009:* *Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)* *Jan. 2010:* *Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.* *Jan. 2010:* *AB 977 passes out of Assembly Health Committee* *Board reaffirms "support" position.* *April 2010:* *Board changes position from "sponsor" to "support".* *June 2010:* *AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy. Bill died in committee.*

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

Oct. 2007: *Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*

Apr. 2008: *First public forum held in Fremont.*

May 2008: *Staff develop survey form to distribute to consumers to solicit input*
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.

June 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

July 2008: *Staff attends community events, interview attendees about prescription label and distribute surveys.*

Oct. 2008: *Staff continues to attend community events, interview attendees about prescription label and distribute surveys.*
Public Education Committee updated on the status of survey results.

Feb. 2009: *Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.*

May 2009: *Bill passes out of the Senate*

Oct. 2009: *Governor signs SB 470 (Chapter 590, Statutes of 2009).*

Oct. 2009: *Board approves regulatory language for notice.*

Nov. 2009: *Regulatory effort initiated.*

June 2010: *Board adopts final text (See Objective 3.2, Task 16).*

Nov. 2010: *Office of Administrative Law approves regulation.*

Jan. 2011: *Regulation takes effect.*

9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.

Dec. 2008: *Board receives findings of independent fee audit.*

Jan. 2009: *Board votes to pursue fee increase.*

Feb. 2009: *Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.*

June 2009: *Bill passes out of the Assembly.*

Sept. 2009: *Bill is enrolled and sent to the Governor.*

Sept. 2009: *Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.*

Oct. 2009: *Governor signs AB 1071 (Chapter 270, Statutes of 2009)*

Jan. 2010: *Statutory fee schedule implemented (supersedes 16 CCR 1749)*

10. Advocate legislation to enhance the board's enforcement activities.

Jan. 2010: *Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):*
Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.
Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

2nd Qtr 10/11: *Board approves provisions for sponsorship in 2011/2012 Session.*

(1) Enforcement Enhancements

- *Section 4104 – Amend to clarify that a pharmacy shall provide to the board, within 14 days, evidence of a licensee's theft or impairment. Require the pharmacy to conduct an audit to determine the scope of loss, and to provide the board with a certified copy of the audit results.*
- *Section 4105 – Amend to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.*
- *Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation.*

(2) Pharmaceutical Waste – Reverse Distributors

- *Section 4040.5 – Amend to specify that a reverse distributor may not accept previously dispensed medicine and specify that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler.*
- *Section 4081 – Amend to specify what records must be maintained of drugs being returned to a wholesaler or reverse distributor; and specify information that is to be maintained for drugs that are returned via a licensed integrated waste hauler.*
- *Section 4126.5 – Amend to authorize a pharmacy to furnish drugs to a licensed integrated waste hauler for the sole purpose of disposing of pharmaceutical waste returned to a pharmacy.*

3rd Qtr 10/11: *SB 431 is introduced containing – amendments to 4104, 4105, and 4112.*

4th Qtr 10/11: *SB 431 amended to also contain changes to 4081, 4126.5, and 4126.7.*

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (§ 1793.7-1793.8). *Jan. 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (§ 1713 and 1717(e)). *Jan. 2007:* *Regulation takes effect following approval by the Office of Administrative Law.* 3. Make technical changes in pharmacy regulations to keep the code updated. *April 2007:* *Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.* *June 2007:* *Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.* 4. Repeal the requirement to post a notice regarding electronic files (§ 1717.2). *March 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* 5. Revise and update Disciplinary Guidelines (§ 1760). *Oct. 2007:* *Board approves regulation for 45-day comment period.* *May 2009:* *Regulation and revised Disciplinary Guidelines approved and takes effect.* *July 2011:* *Discussion to update Disciplinary Guidelines to also incorporate recommendations of the Substance Abuse Coordination Committee.* 6. Self-assessment of a wholesaler by the designated representative (§ 1784). *April 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.* *March 2011:* *Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-26 (See Objective 3.2, Task 24)* *Board notices regulation for 45-day comment period.* *May 2011:* *Board adopts regulation.* *June 2011:* *Rulemaking submitted to Department for review.* 7. Exempt the address of records of interns from display on the board's Website (§ 1727.1). *Sept. 2006:* *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.* 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. *July 2006:* *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.* *June 2007:* *Board staff submit rulemaking file to the California Building Standards Commission.* 9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(§ 1707.2). *Feb. 2007:* *Board notices regulation for 45 days comment period.* *Nov. 2007:* *Regulation changes takes effect.* *Jul. 2008:* *Board mails updated Notice to Consumers to all pharmacies in California.* *1st Qtr 10/11:* *Board discusses updates to Notices to Consumers (See Objective 3.2, Task 25)* *May 2011:* *Board approves language to revise Notice to Consumers (See Task 19.)*

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

Dec. 2007: *Office of Administrative Law approves Section 100 Changes.*
Amend the following:
1707 – Waiver of requirements for off-site storage of records
1709.1 – Designation of pharmacist-in-charge
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge
1717 – Pharmacy practice
1746 – Emergency contraception
1780.1 – Minimum standards for veterinary food-animal drug retailers
1781 – Exemption certificate
1787 – Authorization to distribute dialysis drugs and devices
1790 – Assembling and packaging
1793.8 – Technician check technician
Repeal section 1786 – Exemptions

March 2009: *Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*

11. Increase fees to keep the board's contingency fund solvent and maintain operations.

Nov. 2007: *Office of Administrative Law approves rulemaking.*

Nov. 2007: *Staff complete necessary programming changes and begin advising licensees of the change.*

Jan. 1, 2008: *New fees take effect.*

Oct. 2009: *Governor signs AB 1071, new fee schedule.*

Jan. 2010: *Statutory fee schedule becomes effective (supersedes 16 CCR §1749)*

12. Secure regulatory standards for pharmacies that compound. (§1735 et al)

Nov. 2007: *Board releases language for the 45-day comment period.*

Sep. 2008: *Board releases (withdrawn) language for 45-day comment period.*

Oct. 2008: *Regulation hearing*

Jan. 2010: *Office of Administrative Law approves regulation.*

July 2010: *Regulation and Self-Assessment Form 17M-39 is effective.*
Board staff developing fact sheet for pharmacies.

March 2011: *Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-39 (See Objective 3.2, Task 24)*
Board notices regulation for 45-day comment period to update § 1735.2 and § 1751 and to revise/update the Compounding Self-Assessment form (17M-39).

May 2011: *Board motions to adopt regulation.*

June 2011: *Rulemaking submitted to the Department for review.*

13. Establish an ethics course (§1773 and §1773.5).

Sep. 2008: *Board notices regulation for 45-day comment period.*

Sep. 2009: *Regulation takes effect.*

14. Pharmacist Renewal Requirements (§1702).

Dec. 2009: *Board notices regulation for 45-day comment period.*

Feb. 2010: *Board adopts regulation.*

June 2010: *Office of Administrative Law approves regulation.*

Dec. 2011: *Regulation takes effect.*

15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).

Oct. 2009: *Board notices regulation for 45-day comment period.*
Jan. 2010: *Board adoption of regulation as noticed.*
July 2010: *Rulemaking submitted to the Office of Administrative Law for review.*
Aug. 2010: *Office of Administrative Law approves regulation.*
Sep. 2010: *Regulation takes effect.*

16. Standardized, Patient-Centered Prescription Labels (§1707.5)

Nov. 2009: *Board notices regulation for 45-day comment period.*
Jan. 2010: *Regulation hearing.*
Feb. 2010: *Board modifies text of regulation.*
Board notices modified text for 1st 15-day comment period.
Apr. 2010: *Board modifies text of regulation.*
Board notices modified text for 2nd 15-day comment period.
June 2010: *Board adopts regulation language noticed on April 28.*
July 2010: *Rulemaking submitted to Department for review.*
Oct. 2010: *Rulemaking submitted to the Office of Administrative Law for review.*
Nov. 2010: *Office of Administrative Law approves rulemaking.*
Jan. 2011: *Regulation takes effect.*

17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746)

Jan. 2010: *Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.*
July 2010: *Board begins working with Medical Board to update the EC Protocol.*
May-June 2011: *Executive Officer works with Medical Board (MBC) and others to revise the protocol. The MBC will discuss at its July 2011 meeting. Pharmacy will discuss update of board regulation after MBC approval. The board will also need to update the Patient Information Fact Sheet on EC Protocol.*

18. Board Issued Continuing Education (CE) Credit (§1732.2)

Feb. 2010: *Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.*
Oct. 2010: *Board notices regulation for 45-day comment period.*
Feb. 2011: *Board issues modified text for 15-day comment period.*

19. Notice to Consumers re: Patient-Centered Prescription Labels

Apr. 2010: *Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.*

July 2010: *Board discusses possible language for Notice to Consumers.*

Oct. 2010: *Board discusses possible language for Notices to Consumers. Votes to modify and move existing Consumer Notices from §1707.2 to a new section at 16 CCR §1707.6, to include language for increased font size and oral interpretive services, and other changes.*

1st - 3rd Qtr 10/11: *Board discusses updates to the Notices to Consumers to incorporate Patient-Centered Requirements.*

March 2011: *Board approves language and directs staff to initiate a formal rulemaking to amend 16 CCR 1707.2 and to add 16 CCR §1707.6; directs staff to issue language for a 45 day public comment period; and to schedule a public hearing for the proposed regulation.*
Board approves language for 45-day comment period and schedules regulation hearing for July 2011.

May 2011: *Board notices regulation for 45-day comment period and notices regulation hearing for July 27, 2011.*

20. Update references to USP Standards (§1780)

1st Qtr 07/08: *Board considers review of USP references.*

2nd Qtr 07/08: *Subcommittee established to conduct full review of USP updates needed.*

21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785)

1st Qtr 07/08: *Board approves regulation for notice.*

2nd Qtr 07/08: *Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.*

22. Accreditation Agencies for Pharmacies that Compound (§1751.x)

1st Qtr 07/08: *Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)*

23. Pharmacist and Intern Pharmacist Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) (§ 1727.2, 1728)

1st Qtr 10/11: *Board approves additional modifications to the Pharmacy Technician Application (Form 17A 5) and directs that the language approved in October 2010 and the application approved February 2011 be issued for a 45-day public comment period.*

2nd Qtr 10/11: *Board votes to require applicants to submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB), and to amend/update the Pharmacy Technician application:*

- *Section 1728 – Amend to require an applicant for the pharmacist examination to submit a Self-Query Report from NPDB-HIPDB.*
- *Section 1727.2. – Add new section to require an applicant for an Intern Pharmacist license to submit a Self-Query Report from NPDB-HIPDB.*
- *Section 1793.5. – Amend to require a Pharmacy Technician applicant to submit a Self-Query Report from NPDB-HIPDB; and to modify the Pharmacist Technician Application (17A-5), incorporated by reference.*

April 2011: *Proposed Text to Amend §1793.5 and modify Form 17A-5 issued for 45 day public comment.*

Oct. 2011: *Board votes to require applicants to submit a Self-Query from the NPDB HIPDB.*

May 2011: *Board notices regulation for 45-day comment period.*

24. Pharmacy Technician Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) and Revise Pharmacy Technician Application (§ 1793.5)

Oct. 2011: *Board votes to require applicants to submit a Self-Query from the NPDB HIPDB and to amend/update the Pharmacy Technician Application (17A-5)*

Feb. 2011: *Board approves additional modifications to TCH application.*

April 2011: *Board notices regulation for 45-day comment period.*

June 2011: *Regulation adopted.*
Rulemaking submitted to the Department for review.

25. Update of Self-Assessment Forms

March 2011: *Board notices regulation for 45-day public comment period to update 16 CCR §1715, §1735.2, §1751 and §1784 and the self assessment forms incorporated by reference:*
17M-13 Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment
17M-14 Hospital Pharmacy Self-Assessment
17M-26 Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment
17M-39 Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

May 2011: *Board approves rulemaking.*

June 2011: *Rulemaking submitted to the Department for review.*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	1. Initiate review of the pharmacist-in-charge requirement. *Aug. 2007:* *Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.* *Oct. 2007:* *Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.* *Jan. 2008:* *Board approves omnibus language recommended by Legislation and Regulation Committee.* • *Section 4022.5 – Designated Representative; Designated Representative-in-Charge* • *Section 4036.5 – Pharmacist-in-Charge* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* • *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action* • *Section 4329 – Nonpharmacists; Prohibited Acts* • *Section 4330 – Proprietors; Prohibited Acts* *April 2008:* *The following provisions are not incorporated into omnibus bill.* • *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.* • *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications* • *Section 4160 – Wholesaler Licenses* • *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* *Sept. 2008:* *Governor vetoes SB 1779.* *Jan. 2009:* *Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821.* *Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.* *Sept. 2009:* *SB 819 and SB 821 enrolled and sent to the Governor.* *Oct. 2009:* *Governor signs SB 819 and SB 821. Provisions go into effect January 2010.* 2. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746) *July 2010:* *Board begins working with the Medical Board to update the EC Protocol.* 3. Initiate review of Pharmacist-in-Charge Requirements. 4. Review of Continuing Education for Pharmacists in Specific Areas. *1st Qtr 10/11:* *Board moves to pursue implementation of CE for specific content areas.*